Patient Information and Consent Form for the Research Project

Magnetic Resonance to Manage Breast Disease

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You are invited to take part in a research project defined above. This project is being conducted by researchers from the Translational Research Institute alongside the Princess Alexandra Hospital and the Health and Biomedical Innovation, Queensland University of Technology. This study is being conducted in order to better understand Breast Disease. Please read all information provided prior to signing the consent form.

Background

Breast cancer is the most common cancer in women in Australia and the second most common cancer to cause death in women, after lung cancer. The symptoms of breast disease include new lumps, thickening in the tissues including under the arm, nipple sores, nipple discharge, dimpling of the skin and red or swollen breasts. The cause of breast cancer is unknown, but risk factors include; increasing age, family history, inheritance of mutation in the genes BRCA1 and BRCA2, exposure to female hormones and obesity.

Informed Consent

This Participant Information form contains detailed information about the research project and explains all the procedures involved. Knowing what is involved will help you decide if you wish to take part in the research.
Please read this information carefully and ask any questions you may have about this study. Participation is voluntary. If you don't wish to take part, you don't have to. Your decision will not affect the care you receive.
Once you know what the project is about and if you agree to take part, you will be asked to sign the Consent Form. By signing the Consent Form, you indicate that you:

- understand the information;
- consent to take part in the research project;
- consent to have the tests that are described;
- are willing to provide the study with the name and contact information of your general practitioner upon request;
- consent to the use of your personal and health information as described.

You will be given a copy of the Participant Information and Consent Form for your records.

Study Purpose

It is important to detect and diagnose any changes to the breast as early as possible. This study aims to utilise Magnetic Resonance Imaging (MRI) is a non-invasive diagnostic test to aid in early detection. MRI uses a magnetic field, radio frequency pulses and a computer. MRI

produces detailed pictures of organs, soft tissues, bone and other internal body structures. The data for Magnetic Resonance Spectroscopy (MRS) is recorded using a MRI scanner. MRS is used to determine chemical properties of molecules in cells and tissues. MR spectroscopy can provide detailed information about the nature and chemical environment of molecules.

For those women who hold the BRAC1 or BRAC2 mutation, MRS has the potential to identify the chemical changes in the breast tissue that is not seen when using conventional MRI methods. These changes could identify not only early signs of breast disease, but also location which will aid in surgical intervention.

You are also invited to participate in an optional sub-study investigating if biomolecules expressed from breast tumors can be found in saliva like other various cancers. Both participants without breast disease and participants who have been diagnosed with breast disease are invited to participate in this sub-study. Currently, there is no reliable test to detect breast cancer other than a biopsy of the lesion. Your donated saliva will be processed to identify possible biomarker profiles. Spitting into a cup or chewing onto a diagnostic strip could one day be an alternative to blood testing.

What does Magnetic Resonance Imaging and Magnetic Resonance Spectroscopy Involve?

If you are confirmed to be eligible to proceed on to have the imaging of your brain then the research nurse will arrange an appointment visit for you at one of the following facilities:

- Herston Imaging Research Facility, Royal Brisbane and Women's Hospital campus, Bowen Bridge Road, Herston
- Princess Alexandra Hospital Medical Imaging Department, Ipswich Road, Woolloongabba
- Hunter Medical Research Institute Imaging Centre, John Hunter Hospital campus Newcastle, Lookout Road, Newcastle

During your visit to the imaging facility you will be required to undergo two non-invasive imaging procedures with a clinical scanner used for routine testing. Your two scan procedures will be done in a single visit on the same day with a short break in between.

For the 1st MRS scan you will require to lie in the scanner for approximately 40 minutes. During this scan images of your brain and information on its chemistry will be obtained.

The 2nd MRI scan is a functional MRI and will assess the blood flow in different areas of your brain. This scan will take approximately 45 minutes. These are additional MR scans which you would not be undergoing unless you were part of the study.

As it is unknown how pregnancy may affect chemical changes, pregnant females cannot participate in this study. So if you are a female participant of child bearing potential and you suspect you may have become pregnant prior to attending for your imaging appointment you will be asked to contact the research nurse who will arrange for you to have a urine pregnancy test.

The major discomforts of an MRI are that the scanner is noisy. You will be offered earphones to reduce the noise. Some people may experience symptoms of claustrophobia from lying in a confined space. Should you feel discomfort or become distressed while lying in the MR scanner the healthcare specialist working with you at that time will provide information and

advice regarding additional support and/or referral for your particular concerns. You can signal at any time that you wish to be stop the scan and the healthcare specialist will stop the scan and assist you.

What does participation in this research involve?

You will need to return a signed consent form prior to participation. Upon return of the consent form you will be asked to participate in the following;

If you are scheduled for surgery;

A biopsy or a small piece of tissue will be collected by your surgeon prior to surgery for the purpose of this study. This tissue will be examined under Magnetic Resonance Spectroscopy. After your biopsy, you will also be provided an appointment time at the imaging facility closest to you to complete a MRI and MRS of your breasts.

If you are a volunteer who is identified as carriers of BRAC1 and/or BRAC2;

If you have an unconfirmed BRCA genetic status, you will be asked to provide blood for analysis. Blood collection will be completed with either the relevant hospital's blood collection services or at the Clinical Research Facility. The amount of blood collected for BRCA genetic testing is 16mls.

You will then be provided an appointment time at the imaging facility closest to you to complete a MRI and MRS of your breasts. Along with your regular clinician, the study will provide yearly follow up imaging for further monitoring for the entirety of the study.

NB: If abnormalities in the tissue are detected, your referring doctor will be notified and you may require a biopsy.

If you are a healthy volunteer or do not carry the gene(s) or have not been diagnosed with breast cancer;

If you have an unconfirmed BRCA genetic status, you will be asked to provide blood for analysis. Blood collection will be completed with either the relevant hospital's blood collection services or at the Clinical Research Facility. The amount of blood collected for BRCA genetic testing is 16ml.

Once confirmed that you do not carry the BRCA1 or BRCA2 gene, you will then be provided an appointment time at the imaging facility closest to you to complete a MRI and MRS of your breasts.

What does participation in the saliva optional sub-study involve?

This study requires participants who have been diagnosed with breast cancer and also healthy volunteers. You can be involved in the sub-study in one of two ways; you can donate salvia only or you can donate salvia and a blood sample.

When donating salvia, please do not eat or drink (expect for water) for at least one hour prior to donating saliva. This includes also reframing from chewing gum. You will be given a collection jar and asked to spit 1-5ml into the jar.

If you are willing to also donate blood to the saliva sub-study is 30ml. The blood sample is taken via a simple blood test.

The specimen(s) will be analysed and stored at the Institute of Health and Biomedical Innovation (IHBI), Queensland University of Technology. Once analysis is completed, the specimens will be held at IHBI for 15 years and then destroyed.

What if I withdraw from this research project?

If you decide to withdraw, please notify a member of the research team about your decision. Your decision will not affect your routine treatment, your relationship with those treating you or your relationship with the site. Any identifiable personal information will be destroyed while de identifiable data will be used for the study purpose only.

Possible Benefits

A benefit of participating in the study is ongoing follow up for those who are identified as carriers of BRCA1 and BRCA2 genes. This may mean that any breast disease is identified sooner improving your outcomes. For those who require surgery, MRI and MRS can assist the surgeon in his decision on how much of the tissue is effected therefore how much tissue to remove.

You can request an individual summary of your MRI results. This summary might be beneficial to you in terms of your medical history.

Possible Risks

There are no known risks associated with standard MR procedures, unless you have any electrically, magnetically or mechanically activated implants or vascular clips, metallic plates, cardiac stents or metal fragments in your body. If you have any of these types of implants or you suffer from claustrophobia you will not be not be able to participate in this study.

Incidental Findings

If during the study any abnormalities are identified in your scans that require immediate attention or follow up, the clinical principal investigator will make contact with your local doctor to discuss the finding and if required will arrange a referral to an appropriate specialist. Any incidental finding as part of this research study may require you to have repeat imaging tests in a clinical setting

For those who have been identified as carriers of the BRCA1 or BRCA2 gene during the course of this study, your results will be forwarded onto your General Practitioner and you will be provided with follow-up for the remainder of the study.

Specimen Storage

Breast lesion samples will be destroyed after MRS analysis.

If you are participating in the saliva sub-study, the specimen(s) will analysed and stored at the Institute of Health and Biomedical Innovation (IHBI), Queensland University of Technology.

Once analysis is completed, the specimens will be held at IHBI for 15 years and then destroyed.

Privacy and Confidentiality

All personal and health information obtained throughout the study will remain strictly confidential as required by law. Any information collected in identifiable form will only be accessible to the principal investigator and the relevant research staff assigned to the study. All data collected will be de-identified and your name will be replaced unique participant number.

If you are identified as having breast disease during the course of this study, the information collected will be passed on to your general practitioner and breast specialist after obtaining your permission.

All information obtained during this research study may be subject to inspection by an authorised representative of the approving ethics institutions. The purpose of these inspections is to verify procedures and the data. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

All data collected during the study will be stored in a secure location in either electronic or paper format. De-identified data will be stored in an encrypted electronic database and stored indefinitely. Paper recorded will be stored securely in accordance with the Australian Regulatory Guidelines and then destroyed 15 years after study completion.

Disclosure of Results
It is anticipated that the results of this research study will be published and/or presented in a variety of forums. No identifiable information will be used in publication of the results. Your information will only be used for the purpose of this research study and will only be disclosed with your permission, except as required by law.

Remuneration
Although the study will not cover travel costs associated with participation in the study, parking vouchers will be supplied to you when you attend for your appointment at either the Herston Imaging Research Facility or the Princess Alexandra Hospital Medical Imaging Department.

Further information and complaints

If you would like any further information, or have questions or concerns about participation in this study you can contact these members of the study team.
Professor Peter Malycha (Clinical Principal Investigator) - 07 3443 7813
Lisa Rich (Research Nurse, Clinical Research Facility) – 07 3176 9002

The ethical aspects of this research study have been reviewed and approved by the Metro South Health Human Research Ethics Committee (HREC/15/QPAH/298).

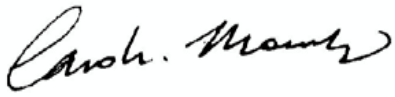
If you have any complaints about any aspect of this study, the way it is being conducted or any questions about your rights as a research participant, then you may contact Metro South Health HREC Coordinator on 07 3443 8047 or ethicsresearch.PAH@health.qld.gov.au

Withdrawing from the study
You can withdraw from the study at any time by contacting the clinical principal investigator and inform him of your decision. Your decision to withdraw from the study, will not affect your relationship with the Translational Research Institute or the hospitals involved.

Ethical Guidelines
This study is being be carried out in accordance the *National Statement on Ethical Conduct in Human Research* (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

If you would like to participate, please complete the consent form below and return it directly to the study team. A member of the study team will then contact you directly to arrange an appointment convenient to you, so the assessments can be completed.

Thank you for considering this invitation.



Professor Carolyn Mountford,
Chief Investigator

partnering for better health

Magnetic Resonance (MR) to Manage Breast Disease

Consent Form

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Declaration by the participant:

- I have read the Participant Information or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research described.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study without affecting my future health care.
- I am aware that if I do withdraw at any point, my personal information will be removed, and any de-identifiable data will remain within the study.
- I authorise assigned study personnel and any authorised representatives of approving institution to access my personal or health information collected for the purposes of this study.
- I understand that all electronic data collected including contact details will remain on an encrypted database.
- I understand that my personal and health information will remain confidential, except as required by law.
- I understand that my local doctor (GP) may be contacted about my participation in the study and that information gathered during the course of the study that is relevant to my ongoing healthcare will be passed on as required.
- I understand I will be given a copy of my signed consent form to keep for my records.

Full Name_____ **Signature** _____

Date and time of Signature _____

Optional Additional Participant Consents

☐ Yes	☐ No	I consent to the use of de-identified images of my breast MRI and MRS in any publications and presentations relevant to this research.
☐ Yes	☐ No	I would like to receive personal, individual feedback on the results of my imaging.
☐ Yes	☐ No	I would like to receive a summary of the overall finding of the study when it has been completed.
☐ Yes	☐ No	I consent to the use of my de-identified data collected during this study to be used in future research of a similar nature.
☐ Yes	☐ No	I agree to allow researchers from the Translational Research Institute to contact me to participate in any future components of this research study.
☐ Yes	☐ No	I agree to allow researchers from the Translational Research Institute to contact me to participate in any relevant future studies and I understand I am under no obligation to do so

Full Name_____ **Signature**_____

Date and time of Signature_____