**Participant Information Sheet and Consent Form**

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| **Title:** | Psychosocial Aspects of Genomic Testing for Breast Cancer Risk |
| **Principal Investigator:** | [INSERT SITE PI DETAILS] |

1. **What is the purpose of this research?**

This study aims to assess the impact of offering the results of a new test that assess breast cancer risk. This test is called “genomic testing”. For this study we will invite 400 female participants from the “Common Genetic Variants and Familial Breast Cancer” study to receive their genomic testing result.

We will then assess interest in receiving this information. We will also explore participants’ thoughts and feelings about the decision to receive or not receive their test result. We wish to hear from women about their interest in receiving this risk information. We also wish to learn how this information may affect them. We hope this study will help us to understand the best way to offer genomic testing in family cancer clinics.

This research has been funded by the Cancer Council New South Wales and is being conducted by University of New South Wales, in collaboration with family cancer clinics in Victoria and Tasmania.

The results of this study will be used by Ms Tatiane Yanes for aPhD degree at University of New South Wales.

1. **Why have I been invited to participate?**

This study involves women from the “Common Genetic Variants and Familial Breast Cancer” study who have been invited to receive their genomic testing result for breast cancer risk.

It is important for you to understand that we are inviting you to take part in this study, **regardless of your choice about receiving your test results**. That is, even if you decide not to receive your test results, your participation in this study will still make a valuable contribution to our work. The decision whether or not to receive your genomic testing result is completely up to you.

Your choice to receive or not receive your test result will not affect your option to opt-out of the study at any time. That is, even if you chose to receive your testing result, you are free to opt out of the study at any time.

1. **Genomic Testing Result**

Genomic testing is a new technology, and there are no guidelines on how to offer this test in Family Cancer Clinics. Because of this, genomic testing is **not** available in any Family Cancer Clinics in Australia or overseas. This test is only available through research studies, such as this one.

Because of this, the results of your genomic testing will not be available outside of this new study. We are also not able to offer the genomic testing results to everyone in the “Common Genetic Variants and Familial Breast Cancer”. Results will only be available to a randomly selected group of 400 women.

We hope that from this study, new guidelines will be created so that genomic testing can be offered in Family Cancer Clinics.

1. **What does participation in this research involve?**

You will be asked to complete up to three questionnaires over a period of 12 months. The first questionnaire will be sent to you as soon as you let us know that you would like to be part of the study. This will be completed by all participants, and **before** an appointment at the family cancer clinic. Questionnaires two and three will depend on your decision to receive or not receive your genomic testing results. You will have a choice of completing mailed or online questionnaires. The first questionnaire will take about 20 to 30 minutes to complete and subsequent questionnaires about 5 to 10 minutes.

Another part of this study will include a telephone interview with 30 to 40 participants who chose to receive their genomic testing results. Interviews will be conducted around 4 weeks after the appointment at the familial cancer clinic. Interviews will take around 30-60 minutes. You will be asked questions about your experience and feelings receiving your genomic testing results and familial breast cancer. With your permission, the interview will be audio taped. If you wish to stop the interview you may do so at any time.

If you choose to receive your genomic testing results, we may also ask to record your genetic counselling consultation. The taped consultation will be de-identified and used to examine how this new information is provided to patients by clinicians. You may decline to have your counselling consultation recorded. This will not affect your ability to participate in the study or receive your genomic testing results (for PMCC and RMH only).

There are no costs associated with participating in this research project, nor will you be paid.

1. **What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research. However, through your participation you will provide information that will be used to improve our understanding of how best to offer genomic testing for common risk variants that contribute to breast cancer risk. Results from this study may also be used to develop advice about the care and support provided to individuals who undergo such testing in the future.

1. **What are the possible risks and disadvantages of taking part?**

You will be invited to receive your genomic testing result that assesses breast cancer risk. Genomic testing may raise important issues. For some individuals their test result may indicate an increased risk for breast cancer. This can also include risk for a new, second breast cancer for women previously diagnosed with breast cancer.

You may also feel that some of the questions we ask are stressful or upsetting. If you become upset or you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you become upset or distressed as a result of your participation in this study, the research team will arrange for counselling or other appropriate support.

Any counselling or support will be provided by qualified staff members who are not members of the research team. This counselling will be provided free of charge.

1. **Do I have to take part in this research?**

Participation in any research project is voluntary. If you do not wish to take part, you don’t have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage, without having to give a reason.

If you decide to withdraw, please notify a member of the research team. If you are currently being treated for breast cancer, your decision whether to take part or not, or withdraw, will not affect your relationship with your treating doctors or hospital.

Your decision whether or not to participate in this new study will not affect your current participation in the “Common Genetic Variants and Familial Breast Cancer” study.

1. **How will I be informed of the final results of this research project?**

A summary of the research findings will be made available to you explaining the findings from the research. You will be asked in the first questionnaires whether you would like to receive a report from the researchers**.**

1. **What information will be collected?**

As well as the information you provide by completing the questionnaires and possibly an interview, information about you will be collected from the “Common Genetic Variants and Familial Breast Cancer” study. This includes clinical data (such as personal history of breast cancer), and family history (such as number of family members diagnosed with breast cancer)

1. **What will happen to information about me?**

Any identifiable information that is collected about you will remain confidential and will only be disclosed with your permission, or except as required by law. Results from this study will only be presented to the scientific community and to the public in ways that protects your identify.

All data will be stored securely in locked filing cabinets and password-protected computers. Information will be stored for a minimum of 7 years from the end of the study and then destroyed.

1. **How can I access my information?**

In accordance with Australian privacy laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information, with which you disagree, be corrected.

Please contact Ms Tatiane Yanes on 1800 814 403 if you would like to access your information.

1. **Who has approved this study?**

All research in Australia involving humans is reviewed by an independent group of people called the Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Peter McCallum Cancer Centre Ethics Committee:

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

1. **Further information about this study and who to contact?**

The person you may need to contact will depend on the nature of your query.

If you want any further information about this project or if you have any problems which may be related to your involvement in the project (for example, feelings of distress), you can contact the research assistant for the study on:

Maatje Scheepers-Joynt

Telephone: 03 8559 6193

Email: maatje.scheepers-joynt@petermac.org

Address: FCC Peter Mac Locked Bag 1 A’Beckett St VIC 8006

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

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| Reviewing HREC name: | Peter McCallum Cancer Centre Ethics Committee |
| HREC Executive Officer: | Ethics Coordinator |
| Telephone: | (03) 8559 7540 |
| Email: | ethics@petermac.org |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

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| --- | --- |
| Name: | Insert local contact information |
| Position: | XXX |
| Telephone: | XXX |
| Email: | XXX |

**Consent Form**

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| **Title** | Psychosocial Aspects of Genomic Testing for Breast Cancer Risk |
| **Principal Investigator** | [INSERT SITE PI DETAILS] |

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

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 project as described and understand that I am free to withdraw at any time during the project without affecting my future care.

I understand that I may keep a signed copy of this document.

**Should you choose to receive your genomic testing results, we may also contact you for a follow up telephone interview and ask to record your genetic counselling consultation. You can opt-out of these by ticking the relevant box bellow:**

* I wish to participate in this new study, but please **do not** contact me for an interview.
* I wish to participate in this new study, but please **do not** record my genetic counselling consultation (included on PMCC and RMH consent form only).

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|  | Name of Participant (please): print) | |  | |  |  |  |
|  | | | | | | | |
|  | Signature: |  | | Date: | |  |  |
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