INFORMATION BROCHURE - ALLOCATE

Australian Ovarian Cancer Study

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AustraLian Ovarian Cancer Assortment Trial

Principal Investigator: Prof Michael Quinn, Royal Women's Hospital

This Participant Information Sheet and Consent Form is 7 pages long, please make sure you have all the pages of this document

We are conducting a research study to investigate the causes of chemotherapy resistance in ovarian cancer. This study is part of the larger research program in ovarian cancer that you may be already enrolled in- the **Australian Ovarian Cancer Study (AOCS).**

This Participant Information and Consent Form explains the research project and what is involved to help you decide if you want to take part. If you have already enrolled in the Australian Ovarian Cancer Study (AOCS), you will have read and signed a similar consent form. However, if you want to take part in this specific research study, you will also need to sign this consent form.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local health worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to and this will not affect your involvement in the larger AOCS program, or with your hospital. You will receive the best possible care whether you take part or not. If you agree to be involved, you can decide to withdraw from the study at a later time.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- understand what you have read;
- consent to take part in the research project;
- consent to be involved in the procedures described;

You will be given a copy of this Participant Information and Consent Form to keep.

WHO IS CONDUCTING THE STUDY?

This research study is being conducted by clinicians and scientists at the **Royal Women's Hospital (RWH)**, the **Peter MacCallum Cancer Centre (PMCC)**, the University of Melbourne (UoM) and the Royal Melbourne Hospital (RMH). The study has been approved by the Research Ethics Committees of these institutions in accordance with the guidelines of the National Health and Medical Research Council of Australia. This study has been funded by the Victorian Comprehensive Cancer Centre (VCCC) Personalised Cancer Medicine initiative.

WHY DO YOU WANT ME TO TAKE PART?

We are conducting this study to try to develop more effective approaches to treating ovarian cancer. We are now appreciating that different types of ovarian cancer are actually different types of disease. The challenge is to try and better match a treatment to a woman, based on specific changes in genes and proteins that have occurred within her tumour. This will be relevant to initial treatments, especially for uncommon types of ovarian cancer, but will be particularly important if the tumour comes back, because tumours can change their nature over time.

We want to be able to take tumour tissue sample from you to perform a tumour screen to help us identify changes in the genes and proteins within the cancer. Initially, our work will focus on getting a better understanding of the specific types of changes in ovarian cancer. Over time we hope to use that information to design and implement better treatments for women with ovarian cancer

WHAT WILL BEING IN THE STUDY MEAN FOR ME?

Being in the study may involve the following:

- We ask that you donate 30 mls of blood (approximately 4-6 teaspoons) to carry out testing of the DNA taken from your blood cells. The blood will be stored in a central laboratory. Genetic material (e.g. DNA) may be extracted from the blood to provide information about the normal cells in your body.
- We ask that you give permission for the doctors conducting the study to access your relevant medical and pathology records, including tumour material that has been stored by pathology laboratories, and clinical cancer genetic test results (if applicable)
- If you are about to have surgery, we would also like permission to keep some of the tissue that is removed at surgery and/or abdominal fluid (ascites) if it is drained.
- If you are willing and this can be done safely, we may ask that you undergo a biopsy procedure so that we can take a sample of your ovarian cancer to screen for changes in the tumour that are there now, as these may be different to changes that were there when you were first diagnosed.

DNA will be extracted from your blood and tumour samples, and we will also perform a genetic screen to look for changes or mutations in particular genes we think may be important in ovarian cancer.

All the results from the tests we perform as part of ALLOCATE will be returned to your doctor, so that they can better understand what is happening in your tumour. They will be able to discuss these research findings with an expert panel. At this stage of the project, it is unlikely that there will be a direct benefit to you from taking part in the study. However, there is a small chance that something we find in your tumour may mean that there is a suitable clinical trial you can be a part of.

The results of the ALLOCATE study are likely to help women who have ovarian cancer and other diseases in the future, and to help clinicians and scientists develop a new way to ensure they receive the most targeted therapy.

There will be no cost to you and if you do not want to take part this will not affect your future medical care in any way. You will also be free to withdraw from the study at any stage if you no longer wish to continue.

WHAT IS INVOLVED IN PROVIDING BLOOD, TUMOUR TISSUE OR ASCITES SAMPLES?

A **blood sample** will be collected by a trained nurse; we will collect 20-30ml (about 4-6 teaspoons).

If you are having surgery as part of your standard care, tumour tissue is removed and sent to pathology as part of diagnosis. Providing it doesn't interfere with diagnostic tests, we request that a sample is retained for research purposes.

If you are having **abdominal fluid** (ascites) removed, some of the fluid may be sent for tests. The results of the tests will be available through your doctor, and may be used to plan your care. The remainder of the fluid would be saved for research.

WHAT IS INVOLVED IN PROVIDING BIOPSY SAMPLES?

Biopsies are procedures in which a sample of the tumour is taken for analysis and may be similar to tests done before your cancer was diagnosed. A biopsy may be performed as part of your care. This will be done as a day procedure at the hospital in which a cancer tissue is obtained using a needle, usually through the abdominal wall or into an affected lymph node. A local anesthetic will be used to reduce pain during the biopsy. During this procedure we wish to obtain 2-3 additional needle samples for research purposes.

You will have routine pre-biopsy screening within 24hr of biopsy to ensure the procedure can be performed safely. You will also be required to sign a separate procedure specific consent for the research biopsy, as per hospital guidelines.

WHAT ARE THE POSSIBLE RISKS?

The possible risks involved with taking part in this study are mostly associated with the side effects of withdrawal of blood and the biopsies. As with any blood sample procedure, there is a small risk of bruising and bleeding from the site where the needles are inserted, but we will ensure that bleeding, if any, has stopped before we let you go home.

Biopsy can cause a small amount of bleeding and, in rare cases, severe bleeding. You will be monitored during the biopsy and at regular intervals for at least four hours following the procedure. Provided vital signs and symptoms are stable, you will be discharged. If you have symptoms or signs suggestive of bleeding, you will be admitted to hospital for appropriate medical management. The collection of the additional samples for research slightly increases the normal risks associated with a biopsy performed as part of your care.

Where the biopsy is from the abdominal cavity there is a very small risk of puncturing your bowel (about 1 in 600 chance).

Ultrasound (USS) guided biopsy is the preferred technique as this does not require additional radiation exposure, however, CT-guided biopsy may be performed especially as part of other diagnostic procedures you require.

WHAT IF WE FIND IMPORTANT GENETIC INFORMATION ABOUT YOU?

It is possible that by performing the genetic screen on your tumour sample we may identify new genetic information about the type of cancer you have, why you developed cancer or how it may behave or respond to treatment Your doctor will be given a copy of all the results of our genetic screen, so that they can better understand what is happening in your tumour. They will be able to discuss these research findings with an expert panel.

Some of the genetic information we identify may have significant implications for your family. In particular, by looking at the DNA extracted from your blood sample we may discover some information not only about your risk of developing cancer, but the risk of your family members developing cancer.

If we find such important information, you will be contacted, and we will arrange for genetic counselling to help you understand the possible implications of this type of genetic information. It is then your choice about whether you wish to receive these results. Because this type of information may be important to your family, we will ask you if you want us to contact a member of your family if we cannot contact you. **We will not give any information about you to members of your family without your permission.**

Currently in Australia, genetic testing does not affect your ability to obtain private health insurance (although there may be a waiting period for pre-existing conditions). However, some companies that handle life and/or disability insurance policies may want to know about any genetic testing that has been performed in your family, or that is intended. This means some genetic results may potentially affect you or your family if you want to take out a new life/disability insurance policy, or if you need to update a current one. If you are concerned about these implications, we can arrange for a genetic counsellor to discuss them with you. We will not pass on this information about you to anyone, including your family members, without your written permission unless lawfully obliged to.

HOW IS MY PRIVACY PROTECTED?

When you donate a sample of blood or tissue to this study, or give us permission to access your medical records, we will make every effort to protect your privacy.

- All your samples will be stored securely in such a way that they cannot immediately be identified as having come from you. They will labelled with a unique barcode number so that they do not get confused with samples from someone else. Any data we collect from your medical records will be treated the same way.
- Any identifying information (your full name, address etc) will be stored separately from the samples and information you provide. Access to this identifying information is restricted to a small number of senior members of the study team.
- No information that could be used to identify you or your family will be included in any report on the results of the study.

FUTURE RESEARCH USING YOUR INFORMATION AND SAMPLES

After we have finished this particular study, the **Australian Ovarian Cancer Study (AOCS)** will keep the information and remaining samples that you give us **indefinitely**. In the future we may match your personal data against other health registers and we will use your samples for future biochemical and genetic studies of ovarian cancer. We may also contact you again to ask you to take part in a follow-up study but you will be under no obligation to do so. Any extra studies that use your samples will have to be approved by the Scientific and Ethics Committees at the the institution carrying out the proposed study before your material can be used. Any information or material given to researchers will be identified by a code only so it will not be possible for them to identify you in any way.

You will not receive any notice of future uses of your information or samples, and it is unlikely that you will receive any direct research results from future work. However, if any research findings are made that have significance for you or your family, we will arrange for those results to be returned to you as described above.

There is a chance that information derived from the samples that you are donating under this study may, in the future, have some commercial value, for example if they lead to the development of a commercial product. You will not be compensated for your participation in the study or for any future value that your samples may be found to have. However, it is our intention that if money is generated as a result of research using your samples then some will be put into a special fund to be used for future research into ovarian cancer.

CAN I WITHDRAW FROM THE STUDY?

You may withdraw from the study at any time and this will in no way affect your medical treatment in the future. If you decide now that your tissue and blood can be kept for research, you can still change your mind later. Just contact us and let us know that you do not want us to use your samples. Any blood or tissue (or any products derived from them) that is left in the bank will then be destroyed.

The collection of **biopsy** samples is voluntary. You can change your mind about undergoing the biopsy procedure at any time.

WHAT IF I HAVE MORE QUESTIONS OR A COMPLAINT ABOUT THE STUDY?

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

If you have any medical problems which may be related to your involvement in the project (for example, any side effects) you can contact the principal study doctor (Prof Michael Quinn or Miss Orla McNally) on (03) 8345 2000, **at any time.**

If you have any questions about the study, please contact the Project Managers:

Name	Tiffany Cowie
Position	Project Manager, The University of Melbourne
Telephone	(03) 9035 7914
Email	tiffanyc@unimelb.edu.au

Name	Kathryn Alsop
Position	Project Manager, Peter MacCallum Cancer Centre
Telephone	(03) 9656 1789
Email	kathryn.alsop@petermac.org

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

Complaints contact person – Peter MacCallum Cancer Centre

Name	Patient Advocate
Telephone	(03) 9656 1870

Complaints contact person – The Royal Women's Hospital

Name	Consumer Advocate
Telephone	(03) 8345 2291

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:

Reviewing HREC name	Peter MacCallum Cancer Centre Ethics Committee
HREC Executive Officer	Ethics Coordinator
Telephone	(03) 9656 1699
Email	ethics@petermac.org

CONSENT FOR RESEARCH

I have read this Information Brochure …….. YES ☐

The consequences involved in participation in this research study have been explained to me and I understand these …… YES ☐

I have had an opportunity to ask questions and am satisfied with the answers I have been given …… YES ☐

I _____ (*please print name*) hereby voluntarily consent to:

(1) Participate in the **ALLOCATE** study as described in the Information Brochure: YES ☐ NO ☐

(2) The following samples being collected and used for analysis as described in the Information Brochure:

a. A small (30mls) blood sample …….. YES ☐ NO ☐

b. A biopsy sample …….. YES ☐ NO ☐

d. An ascites sample……... YES ☐ NO ☐

(3) Allow the ALLOCATE researchers access to my:

a. medical, oncology and pathology records (including tissue blocks / slides) from any treatment centres for the duration of the study …… YES ☐ NO ☐

b. clinical cancer genetic test result……... YES ☐ NO ☐

(4) Allow the AOCS researchers to keep this information and any leftover blood and tissue samples for use in future cancer research YES ☐ NO ☐

(5) I understand that I will be contacted if findings are made that have implications for me or my family, and that I will be given some information to help me decide whether I will find out the results YES ☐

(6) If I cannot be contacted, I wish to nominate a relative to be notified of any research results that may be of medical importance to my family. I have/will inform this individual that I have nominated them YES ☐ NO ☐

Name:	**Relationship:**
Address:	**Phone:**

In making my donations I understand that:

- The tissue (including its constituents and anything derived from it) will be stored indefinitely at PMCC and will be used for this and future studies of cancer.
- The samples will be stored in a coded system to maintain confidentiality.
- There will be no cost, nor any financial benefit to me for participating in the study. If my samples lead to the development of a commercial product in the future I will not receive payment for this.
- If at any time I decide that I no longer wish to participate in the study, my samples will be discarded upon my written request to the Study Investigators. This will not affect my future medical treatment.
- The samples will remain in the custody of the PMCC. They will be stored in good faith, but their suitability for future use cannot be guaranteed. Samples will not be used for purposes other than those agreed to in this consent form.
- All studies using my samples will have to conform with the ethical and scientific principles set out by the National Health and Medical Research Council of Australia, the *Privacy Act 1988* and the Guidelines approved under section 95A of the *Privacy Act* (2001). I will not be notified about future use of my samples.
- I may be approached again to participate in future studies but I am under no obligation to do so.

SIGNATURE: **DOB:** **Date:**

Address:

WITNESS: Name: **Signature:** **Date:**

REVOCATION OF CONSENT

If at any time you wish to withdraw from the study please complete this form and forward it to the address below.

- If you ask to withdraw from the study we will not contact you again about the study and this will not affect your future medical care in any way.

- Please also indicate if you would like us to destroy the samples and/or data that you had previously donated to the study or if you are happy for us to keep these *on the understanding that researchers who use them will not be able to identify them as coming from you*.

I hereby wish to **WITHDRAW** my consent to any further participation in the ALLOCATE described above and understand that such withdrawal **WILL NOT** make any difference to my medical care or my relationship with the Hospital or my medical attendants.

I wish you to destroy the following samples and data that I had previously donated to the study:

Blood Sample:	☐	YES, please destroy this	☐	NO, I am happy for you to keep this
Tissue samples:	☐	YES, please destroy this	☐	NO, I am happy for you to keep this
Clinical data:	☐	YES, please destroy this	☐	NO, I am happy for you to keep this

I understand that samples previously donated to the ALLOCATE study will be kept indefinitely by the AUSTRALIAN OVARIAN CANCER STUDY

Signature: _____ Date: _____

Name (please print clearly): _____

Home postcode:

Please forward to:

Kathryn Alsop
The Australian Ovarian Cancer Study
Peter MacCallum Cancer Centre
St Andrews Place
East Melbourne VIC 3001

Fax: 03 9656 141