PARTICIPANT INFORMATION AND CONSENT FORM

Peter MacCallum Cancer Centre

Full Project Title: Tissue donation after death to improve our understanding of the progression from primary stage cancer to metastatic disease; incorporating the **CA**ncer ti**S**sue **C**ollection **A**fter **DE**ath (**CASCADE**) and **BR**east **O**rigin **C**ancer tissue donated **A**fter **DE**ath (**BROCADE**) programmes. HREC 11/102 and 15/24

Project Principal Investigators: Professor David Bowtell, Professor Robin Anderson, Ms Heather Thorne. Peter MacCallum Cancer Centre

This Participant Information Sheet and Consent Form is 10 pages long, please make sure you have all the pages of this document

1. Introduction

We invite you and your family to take part in this research study involving the collection of cancer samples from the body after death. Donated cancer tissue enables research aimed at understanding how cancer spreads, for improving diagnosis and for developing more effective cancer therapies.

This Participant Information and Consent Form will tell you about the research project and explain the procedures that are involved. Knowing and understanding what is involved will help you decide if you want to take part in the research. Please read the information in this document carefully and feel free to ask questions about anything you do not understand or want to know more about. Before deciding whether or not to participate, we suggest you talk with your family members.

Participating in this research is entirely voluntary. If you and your family do not wish to participate, you don't have to. 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 participate 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;
- agree to participate in the research project;
- agree to participate in the research processes that are described;
- agree to the use of your personal and health information as described

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

We would also like to access the details about your cancer treatment from Medicare, and the Pharmaceutical Benefits Scheme (PBS). A separate information and consent form is required to access Medicare and PBS information. By gaining access to this information, we will be able to determine what treatments you have received. This will help our research team understand how you responded to various treatments you were given. You can choose to join the CASCADE/BROCADE project with or without providing consent to Medicare and PBS data access.

2. The purpose of this research project

Unfortunately, not all patients are cured of their cancer, particularly when it spreads to other sites in the body and becomes resistant to treatment. This study aims to understand the spread of breast cancer and resistance to treatment. During life, it is often difficult to obtain tissue samples of

breast cancer when it has spread to different organs. The information gained may also aid our understanding of other cancers.

In this study, we seek permission to obtain and study samples of tissue from patients who have recently died of their cancer. We hope this will provide important information to help design more effective therapies for cancer patients in the future.

This study is part of two research cohorts you might know about. kConFab is a research program where we are attempting to identify genetic and environmental risk factors for breast, ovarian and prostate cancer, and to find the genes that control the growth of tumours and their response to therapy. BROCADE is a project set up to create a bank of breast cancer tissue including secondary (metastatic) breast cancer tissue to allow researchers to better understand how breast cancer spreads, and how and why it becomes resistant to treatment.

Your tissue will be used in research projects run by either one of the cohorts, depending on the clinical features of your cancer.

3. What does participation in this research project involve?

If you decide to take part in this project:

- We ask that you donate 40 ml of blood (approximately 8 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 and tumour cells in your body. We will also use the blood to look for evidence of tumour cells in the circulation.
- We ask that you give permission for the researchers conducting the study to access your relevant medical and pathology records (including tumour material from the pathology archive) and clinical cancer genetic test results (if applicable)
- We may want you to complete questionnaires to provide specific information for research. An example of the kind of questions asked would be about health, diet, and lifestyle. Questionnaires might ask about your medical history and any history of cancer in you and your family.
- As part of this consent we want to let you know that the project may check with existing tissue banks such as the Victorian Cancer Biobank (VCB) for any tissue you may have previously donated. We will simply record that you have donated cancer tissue earlier. Pathology laboratory tissue blocks are also an important source of tissue and we want to let you know that these blocks from your past surgery may be requested. Researchers can then make application to the tissue bank if they wish to use this material as well as the resources collected after death.
- Areas where cancer tissue is growing in your body will be identified after death and removed by specialists who are skilled at performing a post-mortem examination. Some normal tissue for cancer related studies may also be removed.
- The tissues will be used for laboratory studies following approval by an appropriate Human Research Ethics Committee (HREC)
- You will <u>not</u> be paid for your participation in this research. There will be no additional charges to you for participation in this research.

4. What will happen to my donated samples?

Your blood sample will be used to prepare DNA that will be analysed by the researchers at the same time as DNA is prepared from your cancer tissue. Your DNA samples, which will be securely stored, will be coded so that they can be linked with your name. This will be done to enable us to contact your designated next-of-kin if we find information about your cancer that may be of relevance to your blood relatives. Where possible we may attempt to keep cancer cells alive in the laboratory by creating cell lines so that we can test the significance of any findings – for example, the role that certain genes play in controlling resistance to chemotherapy. We will also attempt to

grow pieces of cancer tissue in specially bred mice in a procedure called 'xenografting'. Tissue grown in mice (called Patient Derived Xenografts or PDXs) and cell lines made from these tissues are a renewable supply of cancer samples and will allow researchers to study the behaviour of secondary tumours and to look for any differences between primary and secondary tumours that have spread to different sites in the body. These cell lines can also be used to test new therapies in pre-clinical studies.

Your blood and tissue samples will be primarily stored in the Research Department at the Peter MacCallum Cancer Centre. It is possible that some of the tissue you may donate will be stored in another collaborating institute until required by researchers. Your blood and tissue samples will be labelled with a code number, and your name will not appear on the label.

Researchers will be granted access to your samples only after approval by a Human Research Ethics Committee. The types of research will vary, but will include techniques to identify genes that influence the risk of developing cancer, studies to determine the genes and proteins that influence spread of cancer and resistance to therapy, and the growth and testing in the laboratory of cells derived from cancer samples. We have asked that you consent to a range of studies as the technologies for cancer research are evolving rapidly and we cannot anticipate all uses at this time. The Peter MacCallum Cancer Centre Human Research Ethics Committee will continue to oversee the operations of the CASCADE and BROCADE projects.

For a researcher applying to gain access to the database or to use your samples, the following requirements will be essential:

- The researcher must demonstrate that there are adequate resources, including funding, to complete the project satisfactorily. That will usually mean that the work is funded by a research grant, which means in turn that the project has been subject to strict scientific scrutiny. The project must have been examined by appropriately qualified scientists and judged to be of good scientific merit.
- The Human Research Ethics Committee of the researcher's hospital, university or institution must have approved the project.
- Samples may be sent to researchers overseas for ethically approved studies.
- Research studies with these samples may be performed in academic or industry settings, for example Universities, Medical Research Institutes or Pharmaceutical Companies.
- A researcher who gains approval to use information or samples stored in the database may have access to your pedigree (a diagram of your family tree) if you are already a participant in kConFab
- Clinical details about your cancer and your treatment might be released. However researchers will <u>not</u> be given any information that might identify you. The information and samples are coded and researchers will know you only by a number. In any publication and/or presentation of the research, information will always be provided in a way that does not identify you.

5. What are the potential benefits of this study?

We cannot guarantee that there will be any benefits from this research. However, we may make discoveries that will be of significance to future patients and that could be relevant to your relatives. In the latter case, should you have relatives who wish to be informed of such findings and discuss what their meaning is, you should nominate them and have them sign at the end of this document.

6. What are the possible risks?

Having a blood sample taken may cause some discomfort or bruising. Sometimes, the blood vessel may swell, or blood may clot in the blood vessel, or the spot from which tissue is taken could become inflamed. Rarely, there could be a minor infection or bleeding. If this happens, it can be easily treated.

Information may be obtained that is relevant to your family, for example, the identification of genes that influence the risk of developing cancer. Your family members can choose to receive this

information or not. Any information will be provided by qualified Peter MacCallum Cancer Centre staff who can help interpret the findings.

It is possible that information about your sample will be published in one or more scientific journals. Neither your name nor other personal details will appear in these articles.

7. What does a CASCADE/BROCADE tissue donation involve?

If consent has been given, cancer and normal tissues being donated will be removed after death by a post-mortem examination. A post-mortem examination is an orderly procedure performed by a dedicated specialist. Ideally, the procedure takes place within 24 hours after death, although it can be performed later than this.

A family member, your treating clinician or a member of the palliative care team will notify us when a patient enrolled in the study dies and we will organise the transport of your body to and from the centre where the post-mortem examination is performed, returning your body to the funeral home required by your family.

For this research, the post-mortem examination will involve incisions being made in the skin to provide access to samples. Your cancer specialist will communicate closely with the specialist performing the tissue collection to ensure that the procedure is performed with the minimum amount of manipulation of your body required to obtain the samples. Unless you state otherwise (see '*Conditions to the post-mortem procedure'* on the consent page of this document, pg 7&9), this will as a rule involve large incisions typical of a full autopsy. This usually involves an initial incision made in a "Y" shape from near the shoulders, meeting at the centre of the chest and extending to the abdomen. Where cancer has spread to the brain, an incision through the scalp will also be made. In order to obtain adequate tissue sampling, the post-mortem examination may require removal of whole organs for examination. We may also collect a blood sample. Samples of cancer and normal tissue will be handled and stored for future research by the CASCADE/BROCADE project team.

We may take photographs of tumours or organs at the time of the post-mortem examination, to help us record where the cancer has spread. These photographs will usually be taken after the tissue has been removed from your body. We will not take photos of your face or any other bodily features that could identify you to others. Photographs may be used in presentations or publications but, like all data collected as part of the program, will be carefully presented in a way that hides your identity.

After the post-mortem, your body will be carefully prepared for transfer back to the care of the funeral director. The whole procedure should not affect the ability to have a viewing or open casket funeral, as the incisions will be made in such a way as to minimise visible marks.

If you have concerns about the post-mortem procedure, including the taking of photographs, but would still like to donate tissue, please talk to your doctors about making a conditional donation.

8. What effect will making a CASCADE/BROCADE tissue donation have on funeral arrangements?

The tissue collection procedure should take less than 24 hours, and other than this delay it should not interfere with the course of events associated with a funeral. The procedure should not affect the ability to have a viewing or open casket funeral. The research team will make sure that your body is returned to the care of the Funeral Director nominated by your family as soon as possible so that they can continue to plan your funeral. The study will pay for all costs associated with the transfer of your body to the Victorian Institute of Forensic Pathology for the autopsy procedure and then back to the funeral home chosen by you and your family. The cost of your funeral will remain the responsibility of your family.

9. **When should plans be made to ensure the CASCADE/BROCADE tissue donation occurs after death?**

It is important to make the necessary arrangements well in advance, since you and family members need time to discuss this very important issue. Discussion with your next of kin and family members will also help ensure your wishes are considered. You should state any specific

wishes in writing in the section entitled 'Conditions to the post-mortem procedure' towards the end of this document.

10. Does my doctor need to know that I intend to donate cancer tissue for the CASCADE/BROCADE programme upon my death?

Your family doctor may be asked to complete the death certificate at the time of death. It is important that your doctor is aware of your wish to donate tissues in order to complete the death certificate in a timely manner. In addition, your doctor will provide medical information useful for researchers. By signing the consent section, you agree to your local doctor being notified of your decision to participate in this research project. Information about your participation in this research project may be recorded in your health records.

11. Do I have to take part in this research project?

Participation in any research project is completely voluntary. If you do not wish to participate in the program, you do not have to. If you decide to participate, and later change your mind, you are free to withdraw from the project at any stage.

Your decision on whether to participate or not, or to participate and then withdraw, will not affect your treatment, your relationship with those treating you or your relationship with the Peter MacCallum Cancer Centre.

12. What if I want to withdraw from this research project?

If you decide to withdraw, please tell your doctors or a member of the CASCADE/BROCADE research team and they will send you a "Withdrawal of Consent" form. A "Withdrawal of Consent" form is also attached for this purpose at the end of this consent form, which you can fill in and send to us at any time.

If after your death your family is concerned about your involvement in this research and refuses the procedure to be performed, we will respect their wishes.

13. Could this research project be stopped prematurely?

All research projects, including this one, depend on the availability of adequate research funds. The researchers involved in the project are highly committed and will do their best to secure the necessary funding.

14. How will next of kin be informed of the results of this research project?

As the project proceeds, information that may be relevant to your family could be discovered from your blood or tissue samples. Any significant information will be provided to your designated next of kin by qualified Peter MacCallum Cancer Centre staff, who can help interpret the findings. Upon request, your next of kin will be able to access a report describing the tissue sampling performed at the post-mortem examination. If your next of kin wishes to obtain a copy of the research report, they can contact the Project Manager, who will arrange a time for your clinician to meet with them, and explain the document.

15. What will happen to information about me?

We wish to access information stored in your medical records, and potentially by Medicare and the Pharmaceutical Benefits Scheme (PBS) databases, to confirm details about any cancer diagnosis and treatments you may have received. It is important to remember that you can still be part of CASCADE/BROCADE and not provide consent to Medicare and PBS data access.

If we ask you to complete a questionnaire, we will store the data you provide identified by your unique participant number. Please feel free to decline to answer any questions or approaches.

One person (The Project Manager, also called the Keeper of the Database) is responsible for maintaining the security of the database so that no-one may have access to it, except according to set rules and procedures. Only the Keeper and support staff will have access to your personal details. All these key people understand that they have a duty of confidentiality that must be strictly observed. As your data could be used in the future for ethically-approved research, it will not be destroyed unless you wish us to destroy it at a particular time.

16. What happens if I am injured as a result of participating in this research project?

If you suffer an injury as a result of donating blood as part of this research project, hospital care and treatment will be provided by the public health service at no extra cost to you, if you elect to be treated as a public patient.

17. Is this research project approved?

The ethical aspects of the CASCADE and BROCADE projects have been approved by the Human Research Ethics Committee of the Peter MacCallum Cancer Centre.

These projects will be carried out according to 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.

Who can I contact?

A member of the research team can be contacted 24 hours a day on (03) 855 96821

For further information:

If you want any further information concerning this project or if you have any medical problems that may be related to your involvement in the project (for example, any side effects), you can contact any of the following people:

Name: **Lisa Devereux**

Role: ***Manager, BROCADE and CASCADE***

Telephone: (03) 855 96532

Name: **Heather Thorne**

Role: **Manager, kConFab**

Telephone: (03) 855 96526

For complaints:

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

Ethics Coordinator:

Telephone: (03) 855 97540 *email* ethics@petermac.org

Patient Advocate:

Telephone: (03) 855 97517 *email* patient.liaison@petermac.org

CONSENT DUPLICATE FOR PARTICIPANT TO KEEP

I have read, or have had read to me in a language that I understand, this document and I understand the purposes, procedures and risks of this research project as described within.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the CASCADE and/or BROCADE program concerning my disease and treatment that is needed for this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers that I have received. I freely agree to participate in this research project as described. I acknowledge that my family or next of kin are aware of my wish to participate in this program. I understand that I will be given a signed copy of this document to keep.

By signing this consent, I give permission for storage of my blood and tissue samples, and for these to be used in ethically-approved research

Conditions to the post-mortem procedure:

Participant's name (printed)…….

Participant signature Date

Nominated next of kin to receive information (printed): ……..

Relationship to participant: …….

I wish to receive notification of any clinically significant research results that may be important to me and my family:

☐ Yes ☐ No **Address**:…….

Next of Kin signature as witness:…….
Date : / /

If the witness is not the nominated Next of Kin:

Witness name (printed) : ……..

Relationship to participant:……

Witness signature: Date

* Declaration by researcher: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Researcher's name (printed)…….

Researcher signature :…….Date: / /

* A senior member of the research team must provide the explanation and provision of information concerning the research project**.Please ensure all parties sign the original consent document on page 9**

WITHDRAWAL OF CONSENT FORM

(TO BE USED BY PARTICIPANTS WHO WISH TO WITHDRAW FROM THE PROJECT.)

Full Project Title: Tissue donation after death to improve our understanding of the progression from primary stage cancer to metastatic disease; incorporating **CA**ncer ti**S**sue **C**ollection **A**fter **DE**ath (**CASCADE**) and **BR**east **O**rigin **C**ancer tissue donated **A**fter **DE**ath (**BROCADE**) programs

I hereby wish to WITHDRAW my consent and do not wish to donate tissue after death. All data and samples that have been collected as part of my participation in CASCADE/BROCADE will be destroyed. I understand that a record of my consent and my withdrawal of consent will remain stored on the project database.

I understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with the Peter MacCallum Cancer Centre.

Participant's Name (printed) ……..

Signature:……

Date: / /

Please return this form to the CASCADE and BROCADE Project:

Research Division
Peter MacCallum Cancer Centre
Locked Bag #1
A'Beckett Street
Melbourne 8006

Office use only:
Participant ID
_____

CONSENT ORIGINAL

I have read, or have had read to me in a language that I understand, this document and I understand the purposes, procedures and risks of this research project as described within.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the CASCADE and/or BROCADE program concerning my disease and treatment that is needed for this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers that I have received. I freely agree to participate in this research project as described. I acknowledge that my family or next of kin are aware of my wish to participate in this program. I understand that I will be given a signed copy of this document to keep.

By signing this consent, I give permission for storage of my blood and tissue samples, and for these to be used in ethically-approved research

Conditions to the post-mortem procedure: (*for example, please record here if you do not wish photographs to be taken of tissues removed during autopsy)*

Participant's name (printed)……

Participant signature Date

Nominated next of kin to receive information (printed): ……..

Relationship to participant: ……

I wish to receive notification of any clinically significant research results that may be important to me and my family:

☐ Yes ☐ No **Address**:……

Next of Kin signature as witness:……
Date : / /

If the witness is not the nominated Next of Kin:

Witness name (printed) : ……..

Relationship to participant:……

Witness signature: Date

* Declaration by researcher: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Researcher's name (printed)……

Researcher signature :……Date: / /

* A senior member of the research team must provide the explanation and provision of information concerning the research project. **Please ensure all parties sign the Participant Copy on page 7**

THIS PAGE HAS BEEN LEFT BLANK INTENTIONALLY