



Chief Investigator	Professor Stephen Fox	<i>Peter MacCallum Cancer Centre, Melbourne</i>
VIC Contact	Ms Heather Thorne	<i>KConFab National Manager</i>

- *This form has been designed to ensure that your consent is on an informed basis.*
- *Please read and consider each section carefully.*

Your Name and Contact Details

Title/Name	
Date of Birth	
Address	
Telephone	
Email	
Our ID code	

General consent

1. I acknowledge that I will receive a signed copy of this form and the Information Sheet for Participants.
2. I understand that the investigators will conduct this study in a manner conforming with the ethical and scientific principles set out by the National Health and Medical Research Council of Australia.
3. The general purposes and demands of this study have been explained to me.
4. I have read and understood the Information Sheet for Participants.
5. I understand that there will be no additional charges if I choose to participate, nor any financial benefit.
6. I have had the opportunity to consider whether or not to participate.

I understand and consent to the following *(cross out whatever does not apply)*

7. The collection of a small amount of blood which will be used to obtain cells so that genetic material (DNA and RNA) can be extracted and stored indefinitely for this study. In some cases, cultures of blood cells may be established so as to provide a permanent source of genetic material.
8. The sample will be used for genetic testing of genes involved in the inherited predisposition to cancer.

9. The testing is completely voluntary and it is possible to withdraw from the testing process at any stage.
10. I understand that I will be asked to complete questionnaires and may be approached in the future to answer similar questions. I am aware that I may decline to answer any particular question.
11. I understand that information obtained during the course of this research study may be published in a form that will not allow participants to be identified.
12. *(if applicable)* I consent to the researcher having access to tissue samples that have been examined for the presence of Cancer.
13. I consent to other researchers associated with kConFab having access to my samples for approved research purposes only. The researchers will not be able to identify myself or other family members by name.
14. I consent to information about me obtained during the course of this study being entered into a database (registry). I understand that details I provide may be confirmed by checking against records from Cancer Registers and Death Records. I understand that the personal information that I provide will be confidential, and will only be identifiable by an ID code. This information therefore will not carry the family name and the only people with access to personal information will be the keeper responsible for the database, staff involved in maintaining the database and the persons responsible for my genetic counselling and medical care.
15. I give permission for my relatives to be approached for them to be offered participation in this study *(please Circle Yes or No)*. I understand that I should approach them first before they are contacted by the research team.

YES **NO**

With regard to genetic testing, I understand the following:

16. The potential benefits and adverse consequences of having a genetic test have been explained to me.
17. The test may not reveal all possible faults (mutations) that may occur in the genes tested, and it is possible that mutations in other yet-to-be-discovered genes may be responsible for an inherited predisposition to cancer in my family.
18. If a genetic test is done when no mutation has been identified in another affected family member, a negative test will provide very limited information and will not necessarily mean that I have not inherited a gene mutation predisposing to cancer.
19. The test may show the presence of a mutation in a cancer predisposition gene, but it cannot accurately predict the age of onset or type of cancer that might develop as a result. Mutations in cancer predisposition genes cause a high, but not a certain, risk of cancer.
20. Test results of one individual can change the estimation of risk for other family members who have not requested testing. As a consequence of this, the test result may have implications for other members of my family and may affect the ability to obtain some types of insurance.
21. At this stage I wish to be informed if there is a test result that may have implications for myself or my family *(Please Circle Yes or No)*. *(If I decide against obtaining test results at this stage, I am free to change my mind. I understand that if I change my mind, the results will be made available to me, but I will need to contact the research team to inform them that I wish to have any test results.)*

YES **NO**

22. Counselling will be available for me after the test result has been given.
23. The test result, and the fact that I have had a test, will not be revealed to any other person or organisation without my written consent (see below), except under subpoena.

24. The results of the test carried out on this sample may be made known if reasonably indicated to:
(please tick the boxes)
- Other family members;
 - The following individual(s);
 - The following doctor(s).....;
- please provide contact details*
- No other individual.

25. The result will be held in the confidential database and will be known by the keeper of the database, staff involved in maintaining the database and those responsible for my medical care and genetic counselling.
26. If a mutation causing cancer predisposition in the family is identified, the details of the mutation may be made available to laboratories which have been asked to test other family members, provided that to do so would not reveal any person's test result without their consent.
27. The sample will remain the property of kConFab. It will be stored in good faith, but its suitability for future use cannot be guaranteed. The DNA sample will not be used for purposes other than those agreed to in this consent form.
28. I understand that I may withdraw from this study at any time without prejudice, and (if requested) my blood sample and questionnaire will be destroyed. I understand that refusal to take part in the study will not affect my medical treatment.

CONSENT FOR RESEARCH as detailed on pages 1-3 of this form

- Dragana Prodanovic (*Doctor or Health Professional*) has explained to me and I understand the consequences involved in participation in this research study.
- I have had an opportunity to ask questions.
- I am satisfied with the explanation and answers to my questions.
- I consent to information regarding my history of cancer being obtained from medical practitioners and associated hospitals.

.....

Signature of Test Subject / Guardian *Date*

INDEPENDENT WITNESS (*someone who is not a member of the research team*)

Name	
Address	

.....

Signature of independent witness *Date*

PATHOLOGY CONSENT

As part of our study of familial aspects of breast cancer, it is necessary for us to obtain additional information about medical conditions for which you have received treatment, and to confirm details about causes of death in your family members. Hospitals and other medical institutions require written permission before releasing this information.

We would appreciate if you would consider completing this section.

Permission to collect personal and family information

I FAMILY ID:

of give permission for Heather Thorne KConFab manager on behalf of Professor Stephen Fox of Peter MacCallum Familial Cancer Centre, to collect and record medical information and if relevant, samples of previously obtained tissue, on myself, and also on deceased family members (listed) whose diagnoses are relevant to this study, and for the appropriate medical practitioners and hospitals to release that material, for use in the above study.

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Signed:.....

Date:.....

Print Name:.....

Date of Birth:.....

EXPLANATION OF TERMS USED IN THIS CONSENT FORM

Genes associated with cancer: Specific genes in which changes (*mutations*) have been associated with an increased risk of cancer. A **gene test** involves analysis of one or more of those genes to determine whether a mutation is present.

Mutation: Change (or fault) in the normal DNA code which may cause disease.

Cancer predisposition gene mutation: Changed DNA code which gives rise to an increased risk of certain cancers.

DNA (*Deoxyribonucleic acid*): The chemical compound of which the genes are made.

RNA (*Ribonucleic acid*): The chemical message from the genes.