1. What is this Project about and why are we asking for your help?

We need 100,000 women to participate in a new research study about breast cancer and other women's health issues.
The large 'pool' of information gathered from women like you will be used to support a wide range of research, undertaken by Australian and international research groups. We have called this the **life**pool Project and every woman can contribute to the project. We will keep you updated about the kinds of research supported by **life**pool but we won't ask your permission to use your samples or information in each separate research study.

Funding to conduct **life**pool has been provided by the National Breast Cancer Foundation (NBCF). The Chief Investigators come from the Peter MacCallum Cancer Centre, BreastScreen Victoria, University of Melbourne and the Royal Melbourne Hospital through Melbourne Health. The Peter MacCallum Cancer Centre Human Research Ethics Committee (HREC) has approved the protocols and documents for the project

It's important to remember that **you are under no obligation** to take part in **life**pool. In addition, should you choose to take part, **you can change your mind and withdraw your consent at a later date.**

2. If you agree to be part of Lifepool, this is how we will look after the information you provide to us

All information is treated with respect and handled in the strictest confidence. **Your information will only be used for the purposes of research into breast cancer or other women's health issues. All information collected from you or about you is given a unique Project code number and your personal identifiers (name and address) are removed. Researchers will not be able to identify you as an individual.**
Only the General Manager of the Project, the Database Manager and one or two senior staff have access to the link between the code number and your name and address.   These people all understand that they have a duty of confidentiality which will be strictly observed. All information will be stored on secure databases housed at the Peter MacCallum Cancer Centre and the University of Melbourne

3. What do we ask of you?

a. **Complete a Questionnaire**
This confidential on-line questionnaire is designed to gather some information about you, your general health and your family's health. The questionnaire will take approximately 30 minutes to complete.
b. **Give permission for your mammogram results to be collected from BreastScreen or other providers.**
c. **Allow Lifepool to check your health status from time to time with state based cancer registries, your medical record if you go to hospital and health related databases including the National Death Index, Medicare records and the Pharmaceutical Benefits Scheme database.**

d. **Give permission for Lifepool to collect any tissue left over from biopsies or surgery you might have if you were to develop breast disease in the future and to collect any tissue that remains from breast surgery you might have had in the past. In both cases, we would get this 'left over' tissue from the Pathology lab after your diagnosis is made and treatment planned.**

More detailed information about these 4 requests can be found in Section 11.

4. What will my information and samples be used for?

We may use your stored samples to measure substances or gene markers that researchers think might be related to the risk of developing breast cancer. It is possible that some markers researchers may wish to study in the future have not yet been discovered.
The stored samples may also be used for studies of how variations in genes (the list of instructions, made up of DNA, in each cell of our body that tell the cells how to work) can influence risk of developing breast cancer. It is likely that many of the gene variations researchers may wish to study in the future have not yet been identified.

We ask you to give your consent for the use of the information and samples you choose to donate in future research. We can’t tell you exact details of this research, but we can tell you that any use of information or samples by researchers will require approval from a Human Research Ethics Committee and The Project Access Committee.   **Life**pool will create a ‘pool’ of data which can be accessed for a range of research projects into breast cancer and other womens’ health issues, but only with approval from these respected groups.

5. What are the benefits of participating in lifepool?

By participating in **life**pool you are making a direct contribution to the course of breast cancer research which has the potential to save lives.   There are real benefits to the community as a whole from this kind of large scale research resource. Each individual participant is unlikely to benefit directly.
If, in the future, research findings are made which may generate commercial income, such income will be used to support further research by returning funds to the NBCF and the Research Institute. There will be no direct financial benefit to either participants or individual researchers associated with **life**pool but the return of income to NBCF and the Research Institute has long term benefits for the community.

6. What are the risks of participating in lifepool?

There is only a small possibility that genetic research using samples which you may provide will yield information of direct importance to <u>your</u> health. This information may benefit you but it may also pose a risk to your ability to obtain **new** life, trauma, disability or credit insurance. We will provide detailed information about all of this if we contact you to consider a blood sample donation.

7. How will I be kept informed?

We will keep you informed about the general progress of **life**pool by sending you a Newsletter. You can contact **life**pool (details in Section 12) at any time if you do not wish to receive this Newsletter.

8. Will I be told the results of research using lifepool information or samples?

Detailed research results will be published in peer reviewed scientific journals and a summarized version will be provided to all Participants in regular **life**pool newsletters. Any research information thought to be of relevance to your health will be carefully examined by an appropriate team of ethical and medical advisors. We will then do our best to contact you by mail so that you can decide if you want to learn more about that information.

9. How do Researchers access information and/or samples?

The information and samples you may choose to provide will be used by researchers from a range of institutions such as Universities, Medical Research Institutes and commercial research groups such as Pharmaceutical companies. For a researcher to gain access to information and/or samples, they must:

- Demonstrate that the Human Research Ethics Committee of the researcher’s hospital, university or institution has approved the project.

- Apply to the Project Access Committee. The Access Committee will carefully review the science of the project and will only release material for use in well-designed, important research. The Access Committee is overseen by the National Breast Cancer Foundation.

10. Where will my information and samples be stored and what will happen if I change my mind?

All health information and questionnaire data will be stored on secure databases housed at the Peter MacCallum Cancer Centre and the University of Melbourne. Any tumour samples collected by **life**pool will be made into wax blocks (called Tissue Microarray blocks) and stored at the Peter Mac.

You are free to withdraw your consent to take part in **life**pool at any time. If you would like to stop or change the way you are currently participating, please contact **life**pool (details in Section 12). You will be sent a form to complete and asked to choose one of three options:

1. You can ask **life**pool not to contact you any more. You will no longer receive any mail, phone calls or emails from **life**pool. We will continue to collect information about you from BreastScreen and other health information providers and check your health status from time to time with state based cancer registries. Samples and information you have already provided will continue to be available for research.
2. You can ask **life**pool to stop collecting any more information about you from BreastScreen and other health information providers. Any information and samples already collected or that you have provided will continue to be available for research. We won't contact you any more.
3. You can ask **life**pool not to contact you any more, to stop collecting any information about you and to destroy any data and samples that have been collected.

11. More detailed information about the things we ask of you

a. Questionnaire: We want to gather information about your health and lifestyle, for example if you exercise, if you smoke or drink alcohol and any past diseases including cancer that you may have had. We are also interested in past history of cancer in members of your immediate family. Not all sections of the Questionnaire will be relevant to all women so the time each woman takes to complete it will vary.

b. Mammogram Results: Mammographic density is the measure of the white (more dense) versus black (less dense) areas on a mammogram X-ray. We know that women vary in their mammographic density and we wish to support research into learning more about mammographic density and breast cancer risk. We will measure mammographic density in collaboration with the Australian Mammographic Density Facility at the University of Melbourne. Depending on the machine used to take your mammogram, we may convert the x-ray film into an image that can be stored on a computer. We ask your consent to borrow the original mammography x-rays from BreastScreen, your doctor or clinic, for scanning purposes. If you attend a BreastScreen centre in the future for another screening mammogram, we will ask the BreastScreen registry to let us know about this.

c. Health Information: We would like to access information in your medical records, such as pathology reports, which may be produced should you develop breast disease in the future. An example of this would be if you needed to have a biopsy taken of your breast tissue for examination by a Pathology laboratory. We will collect up-to-date information on the health of our Study participants by accessing the Cancer Registry in your state. If you provide your consent under point 2 below, lifepool could also collect information about you from the Australian Institute of Health & Welfare National Death Index and through the Department of Health, Medicare and Pharmaceutical Benefits Scheme (PBS) data.

1. *Consent to Participate in **life**pool*: By clicking on the 'YES' button in the 'Do you agree to participate' box you agree to be part of **life**pool and for the data you provide and information collected about you to be used in future research. This allows us to collect your mammogram information, information from your medical record and health databases including state based

cancer registries. We **may** contact you again in the future to ask if you would consider donating a blood or saliva sample, to ask your permission to collect information about you from other health databases like the Medicare system or perhaps to ask you to complete another questionnaire. A future research project may wish, for example, to gather detailed information about diet or work history. **Life**pool, **not** the researcher, would make initial contact with you

A group of participating women will be asked to donate a blood sample, (about 30ml or approximately 2-3 tablespoons). The women we plan to contact will be women who have developed breast cancer and a group of women matched for age who do not have breast cancer. You might be contacted about donating blood within 2-3 years of signing up for **life**pool, but it is possible that we will contact you in 5 or 10 years time. You may not receive a request from **life**pool at all.
You are free to say 'yes' or 'no' to any of these future requests, it is your choice completely.

2. *Consent for release of Medicare and PBS information*: This form is required by the Department of Human Services to allow **life**pool to gather information about your hospital admissions, visits to doctors and any medication you have been prescribed. Without your written consent, the Department of Human Services will not release any information to **life**pool.. We **may** contact you in the future to ask if you are willing to grant this consent and we would send you Consent form 2 at this time.

d. Collection of left over tissue: Whenever a person has surgery or a biopsy, the tissue taken is sent for analysis by a Pathologist. The tissue is placed into wax blocks so that it can be cut and looked at under a microscope. The wax blocks are kept for up to 20 years by the Pathology Laboratory. It is this left over tissue in wax that we ask permission to access

12. Who can I contact if I have questions or complaints?

If you would like any further information about **life**pool or you have questions, please contact the Manager, Lisa Devereux on 03 **8559 6532 or 1800 198 082 or Lifepool@petermac.org**

If you have a complaint, or would like to speak to someone who is not involved in the project, you can contact The Ethics Co-ordinator at **Peter MacCallum Cancer Centre on ethics@petermac.org or by telephone 03 8559 7540**

.