

# INFORMATION BROCHURE

We are conducting a national medical research study to look at the causes of endometrial cancer. **For this study we need to talk to women with endometrial (uterine) cancer and their relatives (if possible), and women who do not have endometrial cancer.** You have been invited to take part in this study and this brochure will tell you what the study is all about. Please read this brochure carefully and discuss any questions you have with a member of the research team. You are also free to discuss this information with your family and friends. You do not have to make an immediate decision, and may withdraw at any stage.

If you agree to take part in the study we will ask you to participate in a telephone interview about your health and lifestyle, and to fill out a questionnaire about your diet. You will also be asked if you will donate a small sample of blood and, if you are about to undergo surgery, some of your tissue that is removed at surgery.

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## WHO IS CONDUCTING THE STUDY?

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The study is being conducted by scientists at the Queensland Institute of Medical Research (QIMR), together with doctors at many of the large hospitals around Australia. The study has been approved by the Research Ethics Committees of all of these institutions in accordance with the guidelines of the National Health and Medical Research Council of Australia.

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## WHY DO YOU WANT ME TO TAKE PART?

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We are doing this national study to try to find out what causes endometrial cancer so we can attempt to prevent it from occurring in future generations of Australian women. We want to enrol more than 2000 women in the study to look at genes and environmental factors that might influence whether or not a woman gets endometrial cancer. If you take part your participation may help us to develop new tests for cancer or new treatments to prevent or cure disease.

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## WHAT WILL BEING IN THE STUDY MEAN FOR ME?

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Being in the study will involve the following steps:

- (1) an interview about your general health, lifestyle and well being, and about the history of cancer in your close relatives. This will be conducted somewhere convenient to you or by telephone and should take 30-60 minutes
- (2) filling out a questionnaire about your diet (which should take 15-20 minutes)
- (3) giving permission for the research staff conducting the study to access your relevant medical and pathology records (including tumour material) and clinical cancer genetic test results (if applicable)
- (4) *if you agree*, we would like to collect a small blood sample
- (5) *if you are about to have surgery*, we would also like permission to keep some of the tissue that is removed during the procedure. If you choose not to give a tissue sample, you are still eligible to participate in this study.

*We may also, **in the future**, ask you to contact your close relatives to see if they would like to be involved in the same study, on the understanding that they can refuse to participate. Note that this is **not** required for your own involvement in the study, and you do not need to agree to do this now.*

There will be no direct benefit to you from taking part in the study, however the results of the study are likely to help people who have cancer and other diseases in the future. 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.

## IF I GIVE A BLOOD SAMPLE, WHAT WILL IT BE USED FOR?

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We will ask your consent to collect a small amount of blood from a vein in your arm (30ml or about 6 teaspoons). If you agree to this and are having surgery the blood sample will be collected at that time. If you are not having surgery, a trained research nurse will take the sample when she sees you or you can have the sample taken by your local pathology lab or GP. There will be no charge to you for this sample to be taken.

We will use your blood sample to do biochemical and genetic tests (see section on Genetic Testing on page 4) to look for factors that may make someone more or less likely to get cancer or that affect how a cancer responds to treatment. We may also use your blood to make long-lived cell lines (samples that are treated to make them stay alive for an indefinite period in appropriate storage conditions), so that the cells in your blood can be used for further biochemical and genetic tests, and will keep some of your sample indefinitely for future research studies (see the section on 'Future Research' below). For example, a number of blood tests are currently done to detect certain types of cancer and it is important to have blood samples from people with and without cancer to develop new tests like these.

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## WHAT WILL BE DONE WITH MY TISSUE?

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If you are having surgery your doctor will remove some body tissue to do some routine tests. The results of these tests will be given to you by your doctor and will be used to plan your care. If there is any remaining tissue available we would like to save this for cancer research. We will not take any extra tissue for this study.

Your tissue will be stored indefinitely in a secure freezer and will be used only by qualified medical researchers for biochemical and genetic studies of cancer. Your tissue samples will be labelled with a unique barcode identification number only, and will not have your name on (see the section on 'How Is My Privacy Protected' below). These studies aim to understand more about what causes endometrial cancer and why treatment seems to work for some women but not for others. We may also use your tissue to make long-lived cell lines. Your tissue will be valuable for this research whether or not you have cancer. These studies have to be approved by the Scientific and Human Research Ethics Committees at the QIMR and must abide by the ethical and scientific principles set out by the National Health and Medical Research Council of Australia.

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## HOW IS MY PRIVACY PROTECTED?

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When you complete a questionnaire or donate a sample of blood or tissue to this study we will make every effort to protect your privacy. However, your identifying information must be retained in addition to details of your health information, to allow accurate analysis and future contact with you if necessary.

- All your questionnaires and samples will be stored securely in such a way that they cannot immediately be identified as having come from you. They will be labelled with a unique barcode number so that they do not get confused with questionnaires or samples from someone else. Likewise, any data generated from your questionnaires and samples during the course of research will be stored under this unique code to ensure confidentiality.
- Any identifying information (your full name, address etc) will be stored separately from the samples and all the information you provide. Access to this identifying information is restricted to a small number of senior members of the study team, and will not be passed on to other researchers.
- No information that could be used to identify you or your family will be included in any report on the results of the study.

## CAN I WITHDRAW FROM THE STUDY?

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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 we will provide you with a "Withdrawal of Consent Form" on which you can indicate whether you want us to destroy your data, and/or samples. Any data, blood or tissue (or any products derived from them, including cell lines) that have been stored will then be destroyed, as you wish.

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## WILL I FIND OUT THE RESULTS OF THE RESEARCH USING MY TISSUE OR BLOOD?

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The results of research done with your tissue or blood are not likely to be available in the immediate future. This is because research can take a long time and must use samples from many people before the results are known. We will not be able to give you the individual results from your samples but everyone who takes part in the Australian National Endometrial Cancer Study will be sent an information update to let you know in general, how the study is going. You can also contact the Study Team at any time if you have any questions about the study. In exceptional circumstances, when we believe that genetic information will be very important for your health or that of your close relatives, we may contact you to advise you to seek help from appropriate health professionals (see Genetic Testing on page 4).

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## FUTURE RESEARCH USING YOUR INFORMATION AND SAMPLES

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After we have finished this particular study we will keep the information and samples that you give us indefinitely. In the future we may match your personal data against other health registers and may use your samples for future biochemical and genetic studies of 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 QIMR at that time, 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.

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, if money is generated as a result of research using your samples, then it will be put into a special fund to be used for future research into endometrial cancer.

## GENETIC TESTING & THE AUSTRALIAN NATIONAL ENDOMETRIAL CANCER STUDY

People respond differently to things they come into contact with such as smoke, alcohol and different foods and medications. We think that the reason people respond differently is partly due to their genes. Some genes may make people more or less likely to become ill when they come into contact with particular factors. We are trying to find out which genes these are, in the hope that this will lead to new treatments that act in the same way as the 'good' genes.

We also think that some people may have a faulty copy of one or more genes that is causing their cancer. This is more likely to occur in a relatively small group of people who develop cancer at an unusually early age, and/or have many close family members affected with cancer. We would like to identify the changes or "mutations" that cause genes to be faulty, and are associated with a greater chance of cancer occurring in some individuals and their close relatives. If you would like more information on cancer that occurs in families, please see our website [www.anecs.org.au](http://www.anecs.org.au) for access to a brochure on this subject, or call the ANECS Helpline on 1800-222-600.

We would greatly appreciate your participation in the genetic part of the Australian National Endometrial Cancer Study. However this decision is entirely your own and you do not have to give us any explanation if you do not want to take part.

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### HOW DO WE GET A SAMPLE OF YOUR GENES?

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DNA is the genetic molecule of life and it carries the hereditary information that underlies the physical and behavioural characteristics of all living things. DNA makes up genes, and genes are arranged into larger structures called chromosomes.

When your blood sample arrives at our laboratory, we extract DNA from it. The purified DNA will then be screened to look for genes that are thought to be related to cancer. If you have in the future, or have already had any other clinical genetic tests for cancer we will seek your permission to access the results of these tests.

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### WHAT IF WE FIND IMPORTANT GENETIC INFORMATION ABOUT YOU?

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It is possible that future research using your sample may result in new genetic information about your risk of getting cancer. If the research findings may have importance for the future health of you or your family (for example if we find that you may have a gene alteration that is linked to cancer), the researchers are obliged to submit a full report to a Scientific Committee who will then consider whether you or your family might benefit from the chance to learn more about this information.

It is your choice whether or not you wish to know of any important results and we will ask you if you want us to tell you if we do find any information that has significant implications for you or your family. We will also ask you if you want information to be given to 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.**

If we find some important information and you have said that you do wish to know of any significant results, we will do our best to contact you again to ask if you still want to find out more about these results. At that time, you would be given genetic counselling about the implications of receiving genetic information and, if you then decided that you wished to obtain your individual results, you would be asked to give a second blood sample so that the research results could be confirmed in an accredited testing laboratory. **We will not be able to give you results directly but, with your permission, we will pass information onto a clinical testing laboratory so that they can easily repeat the test under the appropriate testing conditions.**

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). It is, however, possible that in the future the fact that you have taken part in a study involving genetics may affect you or your family if you want to take out a new health, disability or life insurance policy. For instance, you may have to disclose whether you have attended a genetic counselling service when you apply for a *new* life insurance policy, and this may affect your policy. In addition, if you tell your relatives that we have

written to you informing you we have found genetic information, or you decide to undergo a clinical genetic test and tell your relatives the result, your relatives will have to disclose this when they apply for a *new* life insurance policy, and this may affect their policy. We will not pass on this information about you to anyone, including your family members, without your written permission unless lawfully obliged to. If you would like more information about genetic testing and health insurance please see our website [www.anecs.org.au](http://www.anecs.org.au) for access to a brochure on this subject, or call the ANECS Helpline on 1800-222-600.

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### ARE THERE ANY RISKS IF I PARTICIPATE?

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When a blood sample is taken there is a small chance that you might experience slight bleeding, minor bruising or pain. All blood samples will be taken by trained personnel who are qualified to manage any such problems.

Genetic research in families does have the potential to detect non-paternity or non-maternity. This is likely to occur only very rarely in the course of our studies, and only in instances where we collect material for genetic analysis from several family members. If detected, we will not release any such findings to you or your family members.

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

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If you have any questions about the study, please call our *free ANECS Helpline* on **1800-222-600** or email [ANECS@qimr.edu.au](mailto:ANECS@qimr.edu.au) or contact:

Sue O'Brien (Project Manager) (07) 3845 3541

Or:

Dr Amanda Spurdle (Chief Investigator) (07) 3362 0371

If you have a complaint or would like to speak to someone who is not involved in the study, you can contact:

- the Chairman of the **QIMR Human Research Ethics Committee** by phoning the Secretary on (07) 3362 0259
- A representative from your hospital (see list on page 6)

We would value your participation in this ground-breaking national study.

*Amanda Spurdle*

**Dr Amanda Spurdle (Bsc (Hons), PhD)**

Chief Investigator, Australian National Endometrial Cancer Study

*RD Wright Fellow*

*Head, Molecular Cancer Epidemiology Laboratory,*

*Cancer and Cell Biology Division,*

*Queensland Institute of Medical Research* RD Wright Fellow

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INDEX OF HOSPITAL ETHICS COMMITTEE CONTACTS

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