Government of Western Australia
North Metropolitan Health Service
Women and Newborn Health Service

Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Women and Newborn Health Service, King Edward Memorial Hospital

Title	Patient Initiated Follow-Up in Endometrial Cancer
Short Title	PECAN
Protocol Number	1
Project Sponsor	Women and Newborn Health Service (WNHS)
Coordinating Principal Investigator/ Principal Investigator	Associate Professor Emma Allanson
Associate Investigator(s)	Professor Paul Cohen
Location	King Edward Memorial Hospital

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you have had recent surgery for a low risk endometrial cancer. This means that you have a low risk of having a recurrence of your endometrial cancer. This research project is testing a new way of following up people with low risk endometrial cancer called patient initiated follow-up (PIFU).

PIFU means that you will not have to attend follow-up appointments or your general practitioner (GP) for an examination every few months. Instead, you will receive education about symptoms to look out for, which may suggest that your endometrial cancer could have returned (for example, vaginal bleeding). If you do have any symptoms or are concerned that your cancer may have come back you will be asked to contact the gynaecological cancer clinic and will be offered an urgent clinic appointment.

This Participant Information Sheet/Consent Form tells you about the research project. It explains what is involved. Knowing what is involved will help you decide if you want to take part in the research.

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 doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

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 have the tests and treatments that are described
• Consent 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.

2 What is the purpose of this research?

The aims of the research study is to see if it is possible to recruit patients following surgery for low risk endometrial cancer to patient initiated follow-up (PIFU), and whether PIFU is acceptable to these women. Another aim of the study is to see how many women on PIFU refer themselves back to the clinic.

In other countries PIFU has been recommended after surgery for low risk endometrial cancer but there have been very few research studies performed to assess its impact on quality of life, healthcare costs, and safety. There is a lot that we don't know about PIFU – for example, whether patients prefer PIFU to conventional outpatient clinic appointments or regular routine GP reviews, if it is associated with a lower or higher quality of life, greater anxiety about cancer recurrence, higher or lower healthcare costs, and what the longer term cancer outcomes are. This research study will not answer all these questions because it is a pilot study designed to test the feasibility and acceptability of PIFU. If these are shown, then we hope to conduct a much larger trial in future to assess healthcare costs and long term cancer outcomes.

Patient initiated follow-up is an experimental method of follow-up in Australia. This means that it is not an approved method of follow-up in Australia.

This research has been initiated by the study doctor, Associate Professor Emma Allanson, a Consultant Gynaecological Oncologist and Head of the Department of Gynaecological Oncology at King Edward Memorial Hospital.

This research has been funded by the Australia and New Zealand Gynaecological Oncology Group (ANZGOG) and the Australasian Society of Gynaecological Oncologists (ASGO).

3 What does participation in this research involve?

This is a randomised controlled research project. Sometimes we do not know which treatment or intervention is best for treating or following-up a condition. To find out we need to compare different treatments or types of follow-ups. We put people into groups and give each group a different treatment or type of follow-up. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random).

If you consent to take part in the study, you will be randomised and allocated to either patient initiated follow-up (PIFU) or to standard GP follow-up (regular 6-monthly visits to your GP). We are randomising '2 to 1' so you will have double the chance of being randomised to PIFU compared to standard GP follow-up. You will be asked to complete three questionnaires about your health and quality of life on two separate occasions.

1. At the beginning of the study, after you have been allocated to either the PIFU group or to the standard GP follow-up group.
2. After 12 months, at the end of the study.

If you are allocated to the PIFU group, you may be invited to take part in a sub-study with a researcher who is an expert in quality of life after a cancer diagnosis. This will involve an interview over the phone and will take approximately 45 minutes. The aim of this sub-study is to find out what you thought about PIFU and whether it affected you in ways that you may not have expected. If you are allocated to the standard GP follow-up group you will not be invited to take part in this sub-study.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no additional costs associated with participating in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you free of charge.

You will not be reimbursed for taking part in the research project.

It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

If you decide to participate in this research project, the study doctor will inform your local doctor.

4 What do I have to do?

If you decide to take part in this research study there are no restrictions to your usual lifestyle – you can participate in sport, eat your usual diet, take your regular medication and donate blood if you are a blood donor. You will not be able to take part if you think you will not be able to manage with patient initiated follow-up (PIFU) or if your endometrial cancer is not low risk. If you are randomised and allocated to the PIFU group, you will receive detailed education including written information from the study nurse about the symptoms of endometrial cancer recurrence. You will be provided with written information about how to contact the gynaecological oncology clinic by telephone and/or email so that you can be seen and assessed in a timely way. It is important that you keep these documents somewhere safe in case you need to contact the gynaecological oncology clinic. We suggest that you enter these contact details into your mobile phone.

5 Other relevant information about the research project

We are aiming to recruit 100 participants to this pilot research project which is being conducted at a single site - King Edward Memorial Hospital. The project involved researchers from several organisations working in collaboration including the University of Western Australia, Australia and New Zealand Gynaecological Oncology Group (ANZGOG), Psycho-Oncology Cooperative Research Group (PoCoG) and the Centre for Evidenced-based decision Making (CeMPED) at the University of Sydney, the Centre for Health Economics Research and Evaluation (CHERE), UTS.

6 Do I have to take part in this research project?

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

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with King Edward Memorial Hospital.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive follow-up. If you do not want to take part you will be advised of the recommended follow-up as is our usual practice.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, if you are allocated to the patient initiated follow-up (PIFU) group possible benefits may include reduced anxiety, distress, fear of your cancer returning because you will not be attending the hospital or your GP for appointments and you will save on the costs of travel, parking and time to attend these appointments.

There may be no clear benefit to you from your participation in this research.

9 What are the possible risks and disadvantages of taking part?

If you are allocated to the patient initiated follow-up (PIFU) group, you may experience anxiety/distress/fear of cancer recurrence. You will be given written information that will contain contact details (email address, landline and mobile telephone numbers) of the Western Australian Gynaecological Cancer Service Clinical Nurse Liaison and the PECAN Study Coordinator so that you can refer yourself back to the clinic for clinical review and follow-up at any time after enrollment.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately, if you experience any new or unusual symptoms.

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

12 Can I have other treatments during this research project?

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved.

13 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

14 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:
• Unacceptable side effects
• The drug/treatment/device being shown not to be effective
• The drug/treatment/device being shown to work and not need further testing
• Decisions made in the commercial interests of the sponsor or by local regulatory/health authorities.

15 What happens when the research project ends?

When the project ends if you are allocated to the PIFU group you will be advised to see your GP 6 monthly for the following 2 years and then yearly for the next 2 years as per our routine recommendation for follow-up after a low risk endometrial cancer. If you are allocated to the standard GP follow-up group your follow-up should continue as usual.

You will be provided with a summary of the results of the project in a newsletter which will be circulated via email when the results are available. This may be several months after the project has been completed and possibly up to three years after your enrolment.

Part 2 How is the research project being conducted?

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16 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. All questionnaires and case report forms will be given a unique identity number (de-identified) and will not include information that would allow you to be identified. A unique patient identification number will be generated by computer and identifiable data will only be available to the study investigators. Only de-identified clinical information will be used for statistical analysis and reporting. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums including national and international academic conferences and in medical journals. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, because names, dates of birth, medical record numbers, and any other identifiable information will not be reported.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and Western Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

17 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

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18 Who is organising and funding the research?

This research project is being conducted by Associate Professor Emma Allanson

You will not benefit financially from your involvement in this research project.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to the Women and Newborn Health Service (WNHS), the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

The Women and Newborn Health Service (WNHS) will receive a payment from ANZGOG and ASGO for undertaking this research project.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of the WA Child and Adolescent Health Service (CAHS).

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

Approval to conduct the study at King Edward Memorial Hospital has been given by the Research Ethics and Governance Office at the Women and Newborn Health Service (WNHS), King Edward Memorial Hospital.

20 Further information and who to contact

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

If you want any further information concerning this project or 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 on 08 6458 2222 or any of the following people:

Clinical contact Person

Name	TBA
Position	Research Nurse
Telephone	TBA
Email	TBA

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

Name	Andrea Browning/Sharon Lobb
Position	Oncology Nurse Liaison
Telephone	0434 957 460
Email	oncologyliaisonclinicalnurse.kemh@health.wa.gov.au

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 approving this research and HREC Executive Officer details

Reviewing HREC name	CAHS
HREC Executive Officer	Dr Natalie Giles
Telephone	08 64560516
Email	cahs.ethics@health.wa.gov.au

Local HREC Office contact (Single Site -Research Governance Officer)

Name	Director of Clinical Services at KEMH
Position	Director of Clinical Services at KEMH
Telephone	(08) 6458 2222
Email	

Consent Form - *Adult providing own consent*

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Short Title	PECAN
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Coordinating Principal Investigator/ Principal Investigator	Associate Professor Emma Allanson
Associate Investigator(s)	Professor Paul Cohen
Location	King Edward Memorial Hospital

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Women and Newborn Health Service, King Edward Memorial Hospital concerning my disease and treatment for the purposes of 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 I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior 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.

Name of Study Doctor/ Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation - *Adult providing own consent*

Title	Patient Initiated Follow-Up in Endometrial Cancer
Short Title	PECAN
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Coordinating Principal Investigator/ Principal Investigator	Associate Professor Emma Allanson
Associate Investigator(s)	Professor Paul Cohen
Location	King Edward Memorial Hospital

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Women and Newborn Health Service, King Edward Memorial Hospital.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.