**Participant Information Sheet/Consent Form**

**Study** -*Adult providing own consent*

**Title** A prospective cohort study for success of vaginal hysterectomy with vault suspension compared to Manchester-Fothergill Procedure for utero-vaginal prolapse

**Short Title** The VaMP Study

**Principal Investigator** Dr Lore Schierlitz

**Investigators** Dr Ruth Cameron-Jeffs, Dr Jessica Uebergang, Dr Christine Murray

**Location** Mercy Hospital for Women, Heidelberg

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project. This is because you have pelvic organ prolapse that you are requesting surgical treatment for. The research project is investigating the best approach to prolapse surgery by comparing two procedures, the vaginal hysterectomy and the Manchester-Fothergill Procedure.

Being involved in this research will not change the advice you are given or the operation you choose, but will involve longer follow up and an some increased time commitment.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments 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.
* Intend to present for follow up as outlined in this document

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

**2 What is the purpose of this research?**

Pelvic organ prolapse (POP) is a condition that affects up to 40% of women during their lifetime [1]. 11-20% of women will need surgery in their lifetime [2-4]. The likelihood of repeat surgery is high and ranges from approximately 9-58% at significant costs to you and to the health system [5, 6].

This study will compare vaginal hysterectomy (removal of the uterus and cervix) and The Manchester-Fothergill Procedure (removal of the cervix). Both of these surgeries are performed regularly at this hospital. The choice between them is a decision made between you (the patient) and your doctor.

**3 What does participation in this research involve?**

If you are suitable for surgery for pelvic organ prolapse, you are likely to be eligible for this study. As part of the project, you will complete several questionnaires that assess your condition, which could take around 5-10 minutes. The questionnaires do contain some sensitive questions regarding your sexual health. Please discuss any concerns you have with the research team.

You will choose the type of surgery you prefer after discussion with your doctor. Information sheets regarding the surgery will be provided to assist you in making a decision. Following the surgery, you will be reviewed 6 weeks, 6months, and yearly until 5 years after the surgery where we will ask questions at each visit and perform an examination. If you have any concerns during this time, we would like to see you earlier, so please contact us.

There are no additional costs associated with participating in this research project, nor will you be paid. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

**4 What do I have to do?**

If you consent to be part of this research trial, we will collect additional information from you before, during and after the surgery. Otherwise the care given will not be different than it would otherwise be. Most people require 2 to 3 nights in hospital after the surgery. We routinely see patients 6 weeks after surgery. If there were not any concerns at this time you would normally be discharged to your GP but we will review you at 6 months and then yearly after your operation until it has been 5 years since the operation. If you had any concerns, we would see you promptly.

**5 Other relevant information about the research project**

A total of ***200*** women will participate in this project. This study has been initiated by the researchers as listed above, who are also custodians of the clinical trial protocol and data.

**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 *Mercy Health.*.

**7 What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at this hospital. If you are wanting surgery for pelvic organ prolapse it is likely we will recommend one of these procedures anyway. There are also non-surgical options for prolapse treatment which will be discussed with you. You can also discuss all of the information provided here with your local doctor.

**8 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research; However, possible benefits include increased follow up post-operatively that would not normally be available after prolapse surgery and the knowledge that your participation will help women be better informed regarding the pros and cons of different approaches to surgery.

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

The risks are the same as they would be for anyone undergoing surgical treatment for pelvic organ prolapse. They will not be increased by participating in this study. Risks associated with these surgeries include:

* Bleeding
* Infection
* Blood clots
* Damage to organs, blood vessels and nerves
* Recurrence of the prolapse
* New (stress) urinary incontinence

Information sheets about these procedures will describe them in further details

**10 What will happen to my test samples?**

No tissue samples would be collected for this study. As part of the usual care, anyone undergoing removal of the uterus or the cervix has their tissue sent for analysis by the pathology team to rule out any abnormality in the tissue.

**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?**

It is important to tell your doctor and the research staff about any treatments or medications you may be taking, including non-prescription medications, vitamins or herbal remedies and any changes to these during your participation in the study.

**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 up to the time you withdraw will form part of the research project results. If you do not want us to do this, you must tell us 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 although this is unlikely. These may include reasons such as unacceptable complications from one type of surgery that were unexpected. This is very unlikely as we perform both these surgeries routinely

**15 What happens when the research project ends?**

When this research project ends, if there are no further concerns regarding your pelvic floor health, you will be discharged from the service. Results of this research will be published in a peer reviewed journal and we will convey the results to you at your follow up visits when available.

**Part 2 How is the research project being conducted?**

**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. 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 collected for this research will be retained for use in further related research that has been reviewed and approved by a Human Research Ethics Committee. This is optional and you can indicate in the Consent Form if you consent for this specific research only or consent for this specific research and future related research.

All information collected will be stored using a secure database within Melbourne University called Redcaps. All data will be de-identified and will later be transferred onto a password protected computer database for statistical analyses. After 15 years, all information will be destroyed.

Any information obtained in connection with this research project that can identify you will remain confidential and will only be used for the purpose of this research project. It will only be disclosed with your permission, except as required by law. In any publication, information will be provided in such a way that you cannot be identified. A code will be assigned to your name for data analysis. We then plan to publish the results in a medical journal without any identification of any individual. Information will be provided in such a way that you cannot be identified.

In accordance with the NHMRC (National Health Medical Research Council) National Statement, the Research Ethics Committee is required to conduct audits of research projects from time to time. It may therefore be possible that the Research Ethics Committee which has approved this research, will seek to view a copy of your signed consent form or to contact you, to ensure that the research is being conducted according to the ethical standards required by the National Statement*.* Health records may be inspected by the Therapeutics Goods Administration (TGA).

It is desirable that your family doctor be advised of your decision to participate in this research project. By signing the Consent Form, you agree to your family doctor being notified of your decision to participate in this research project. In accordance with the *Freedom of Information Act* 1982 (Vic), you have the right to access and to request incorrect information held about you be corrected by the Monash Health or Cabrini Hospital.

**17 Compensation**

In the unlikely event 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. You will be eligible for treatment at Mercy Health at no cost to yourself.

**18 Who is organising and funding the research?**

This research project is being conducted by members of the research team listed at beginning of this form. This is an investigator led trial. There is currently no funding for this project.

**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 Mercy *Health*.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (NHMRC 2018)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**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 Pelvic floor department on *03 8458 4500 where someone will be able to direct your query.*

 **Clinical contact person**

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| --- | --- |
| Name | *Dr Lore Schierlitz* |
| Position | *Urogynaecology Consultant* |
| Telephone | *03 8458 4500* |

 **Complaints Contact person**

 **Mercy HREC**

Contact: Administration Officer, Human Research Ethics Committee

 Telephone: (03) 8458 4808

 Email: ethics@mercy.com.au

**Consent Form -** *Adult providing own consent*

**Title** A prospective cohort study for success of vaginal hysterectomy with vault suspension compared to Manchester-Fothergill Procedure for utero-vaginal prolapse

**Short Title** The VaMP Study

**Principal Investigator** Dr Lore Schierlitz

**Investigators** Professor Peter Dwyer, Dr Alison De Souza, Dr Ruth Jeffs, Dr Jessica Uebergang, Ms Elizabeth Thomas, Dr Christine Murray

**Location** Mercy Hospital for Women, Heidelberg

**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 *Mercy Health* 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, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

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

[ ]  I consent for my information to be used in this research only

[ ]  I consent for my information to be used in this research and future related research after it has been reviewed and approved by a Human Research Ethics Committee.

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|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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|  |
|  | Name of Witness\* to Participant’s Signature (please print) |  |  |
|  |
|  | Signature |  |  Date |  |  |
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\* 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.

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|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
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† 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.

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

**Title** A prospective cohort study for success of vaginal hysterectomy with vault suspension compared to Manchester-Fothergill Procedure for utero-vaginal prolapse

**Short Title** The VaMP Study

**Principal Investigator** Dr Lore Schierlitz

**Investigators** Professor Peter Dwyer, Dr Alison De Souza, Dr Yik Lim, Dr LinLi Ow, Dr Kristina Cvach, Dr Ruth Jeffs, Dr Jessica Uebergang, Ms Elizabeth Thomas, Dr Christine Murray

**Location** Mercy Hospital for Women, Heidelberg

**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 *Mercy Health.*

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|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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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.

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**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.

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|  |
|  | 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.