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**Participant Information Sheet/Consent Form**

**Non-Interventional Study** -*Adult providing own consent*

*The Royal Women’s Hospital*

|  |  |
| --- | --- |
| **Title** | **Prevalence and severity of endometriosis at laparoscopic treatment of tubal ectopic pregnancy** |
| **Protocol Number** | N/A |
| **Project Sponsor** | Department of Gynaecology,The Royal Women’s Hospital |
| **Coordinating Principal Investigator/ Principal Investigator** | Dr Stephen Lee / Dr Jennifer Dean |
| **Associate Investigator(s)** | Dr Charlotte Reddington, Dr Michal Amir, Dr Owen Stock, Dr Claudia Cheng, A/Prof Martin Healey |
| **Location** | The Royal Women’s Hospital |

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

**1 Introduction**

You are invited to take part in this research project, **Prevalence and Severity of Endometriosis at Laparoscopic Treatment of Tubal Ectopic Pregnancy.**

This is because you have been diagnosed with a fallopian tube ectopic pregnancy that is unsuitable for medical management by a medication called methotrexate and you have been advised to undergo laparoscopic (keyhole surgery) treatment of the ectopic pregnancy. The research project is aiming to determine the prevalence (the percentage of a population that is affected with a particular disease) and severity of endometriosis at the time of laparoscopic (keyhole surgery) treatment of tubal ectopic pregnancy.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research 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 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 the tests and research 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?**

Research studies have shown that endometriosis increases the risk of future ectopic pregnancy. However, no studies have looked into the rate and severity of endometriosis at the time of surgical treatment of ectopic pregnancy. There are also no studies to see if there is a link between background risk factors for ectopic pregnancy and existing symptoms of endometriosis. The investigators believe that the diagnosis of endometriosis and its severity will help the counselling of patients and help future reproductive planning, especially after taking into consideration other risk factors for ectopic pregnancy and symptoms of endometriosis.

If high rates of endometriosis are found in patients undergoing surgical treatment of ectopic pregnancy, then the investigators will consider conducting further research into treatment of endometriosis at the time of ectopic pregnancy surgery and its effect on endometriosis symptoms and future pregnancy outcomes.

This research has been initiated by the study doctor, Dr Stephen Lee.

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

You may be eligible for this research study if an ectopic pregnancy located in one of the fallopian tubes is diagnosed and laparoscopic (keyhole surgery) treatment of ectopic pregnancy is recommended. You should review the participant information sheet in detail and sign the consent form if you wish to proceed to participate in the research study. You will not be disadvantaged in any way with regards to your medical care if you choose to not participate in the research study.

Your are eligible to participate in the research study if you understand and fully comprehend the patient information sheet and consent form (PICF).

Once the consent form has been signed, you will be asked to complete the pre-operative questionnaire with assistance from the doctor/s arranging and performing the laparoscopic (keyhole surgery) treatment of ectopic pregnancy. The pre-operative questionnaire is estimated to take less than 10 minutes to complete. Surgical findings will be recorded by the surgeon performing the surgery in a separate document/ questionnaire that will take 5 minutes to fill out, following the safe completion of your surgery Your medical records may be accessed to confirm questionnaire findings.

You will be followed up at the post-operative review clinic around 6 weeks after surgery, which is normal protocol following this sort of operation. You will have the opportunity to discuss surgical findings with the reviewing doctor or an investigator at that time., However, no further information for this study will be required of you at this appointment.

There are no costs associated with participating in this research project, nor will you be paid.

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.

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

As this is an information gathering research study with no prescribed intervention, there are no lifestyle or dietary restrictions associated with participation. You can take your regular medications and donate blood if you want to.

If you do not understand or fully comprehend the participant information, you should not consent to being involved in the research study.

The commitments required of the participant are as follows:

* A pre-operative questionnaire to be completed by the participant and the doctor arranging surgery (less than 10 minutes)

In addition, your surgeon will complete a questionnaire at the time of your operation, which will take approximately 5 minutes.

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

The investigators aim to recruit 66 participants to the research study. It is calculated that 66 participants are required to demonstrate that patients with ectopic pregnancy have significantly higher rates of endometriosis at the time of surgery than in the general population. There are no case/control groups and this research study is conducted only at The Royal Women’s Hospital.

To the investigator’s knowledge, this research study is the first of its kind and is therefore not a follow-on or extension study.

**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 *The Royal Women’s Hospital.*

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

You have to been invited to participate in this research project as you have agreed to have laparoscopic (keyhole surgery) treatment of ectopic pregnancy but you do not have to take part in this research project to receive treatment at this hospital.

**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 may include accurate diagnosis and staging of endometriosis, which will help your decisions regarding further management and reproductive planning.

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

This research does not involve any additional interventional treatment, as you are already planned to have laparoscopic (keyhole surgery) treatment of your ectopic pregnancy.

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 about any new or unusual symptoms.

Your participation in this research study may lead to the unexpected diagnosis of endometriosis. If endometriosis is found at the time of your surgery for the treatment of ectopic pregnancy, a referral to the Gynaecology 2 Unit clinic, specialising in endometriosis and other painful gynaecological conditions will be completed with your permission. At that clinic appointment, you may be offered further tests or treatment options.

Diagnosis of endometriosis as a result of participation in this research study may make endometriosis a pre-existing condition for the future application and purchase of private health insurance.

No ionising radiation will be administered as part of this research study.

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

If you have been invited to participate in this research study, you should have been diagnosed with a tubal ectopic pregnancy and arranged to have keyhole surgery treatment of the ectopic pregnancy.

Laparoscopic (keyhole surgery) treatment of tubal ectopic pregnancy most commonly involves the removal of the fallopian tube that the ectopic pregnancy is located within. The removed fallopian tube and the ectopic pregnancy contained within it is routinely sent to the hospital pathology service for confirmation of the diagnosis. If you are having the less common procedure of salpingotomy, a cut is made in the fallopian tube at the site of the ectopic pregnancy and the ectopic pregnancy is removed from the fallopian tube. In this case, the removed ectopic pregnancy is sent to the hospital pathology service for histological confirmation. All tissue is discarded after histological examination.

No tissue is stored for current or future research purposes.

No genetic testing will be conducted on the tissue(s) collected.

**11 Can I have other treatments during this research project?**

Whilst you are participating in this research project, you are able to take all of the medications or treatments you have been taking for your conditions. However, 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. This information is important for the researchers as it is important to know about your general health, which improves the quality of our research. You should also tell your study doctor about any changes to these during your participation in the research project.

**12 What if I withdraw from this research project?**

If you decide to withdraw from this research project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any 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 investigators 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.

**13 Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. These may include stronger than expected results leading to the early conclusion of the research study, or the publication of a similar study by other researcher, which would reduce the research study usefulness. Should the project stop unexpectedly, this will not impact on you or your care in any way.

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

You will be followed up at the post-operative review clinic according to protocol at around 6 weeks after surgery. You can choose to discuss surgical findings with the reviewing doctor or an investigator, but no further data collection will be required.

A summary of the results of the research study will be emailed to you when study concludes and the findings written up. Please inform the investigator if you prefer not to receive this information.

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

**15 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. There are only 2 instances when your personal healthcare information is collected – the completion of the pre-operative questionnaire and the completion of the intra-operative questionnaire. The questionnaires only contain your hospital Unit Record number and does not contain any identifiable information. The electronic questionnaires are securely transmitted to SurveyMonkey servers through secure channels, encrypted and stored. The information is accessible only through 2-factor authentication by one person only, the principal investigator. 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 research team accessing health records if they are relevant to your participation in this research project.

Your health records and any information obtained during the research project are subject to inspection for the purpose of verifying the procedures and the data. This review may be done by the relevant authorities and authorised representatives of the Sponsor, The Royal Women’s Hospital, the institution relevant to this Participant Information Sheet, The Royal Women’s Hospital, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant research personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

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

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research 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.

**16 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.

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

This research project is being conducted by Dr Jennifer Dean and Dr Stephen Lee

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

**18 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 Royal Women’s Hospital.

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

**19 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 0409 735 232 or any of the following people:

**Clinical contact person**

|  |  |
| --- | --- |
| Name | *Dr Jennifer Dean* |
| Position | *Resident Medical Officer* |
| Telephone | *03 85345 2000, pager 952156* |
| Email | *Jennifer.dean@thewomens.org.au* |

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**

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| --- | --- |
| Name | *Royal Women’s Hospital Consumer Advocate* |
| Telephone | *8345 2290* |

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

|  |  |
| --- | --- |
| **Title** | ***Prevalence and severity of endometriosis at laparoscopic treatment of tubal ectopic pregnancy*** |
| **Protocol Number** | *N/A* |
| **Project Sponsor** | *Department of Gynaecology, The Royal Women’s Hospital* |
| **Coordinating Principal Investigator/**  **Principal Investigator** | *Dr Stephen Lee / Dr Jennifer Dean* |
| **Associate Investigator(s)** | *Dr Charlotte Reddington, Dr Michal Amir, Dr Owen Stock, Dr Claudia Cheng, A/Prof Martin Healey* |
| **Location** | *The Royal Women’s Hospital* |

**Consent Agreement**

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 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 project without affecting my future health care.

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

**Declaration by Participant – for participants who have read the information**

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

**Declaration - for participants unable to read the information and consent form**

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| Witness to the informed consent process  Name (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.

|  |  |  |  |  |  |  |
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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, 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** | ***Prevalence and severity of endometriosis at laparoscopic treatment of tubal ectopic pregnancy*** |
| **Protocol Number** | *N/A* |
| **Project Sponsor** | *Department of Gynaecology, The Royal Women’s Hospital* |
| **Coordinating Principal Investigator/**  **Principal Investigator** | *Dr Stephen Lee / Dr Jennifer Dean* |
| **Associate Investigator(s)** | *Dr Charlotte Reddington, Dr Michal Amir, Dr Owen Stock, Dr Claudia Cheng, A/Prof Martin Healey* |
| **Location** | *The Royal Women’s 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 The Royal Women’s Hospital.

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

Description of event if the participant chooses to convey the decision to withdraw from the research study verbally:

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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.