**Participant Information Sheet/Consent Form**

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

The Royal Womens Hospital

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| **Title** | Anogenital Distance in Adult Women Study |
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| **Protocol Number** | Protocol version 0.5 |
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| **Principal Investigator** | Dr Thomas Kavanagh |
| **Associate Investigator(s)** | Dr Charlotte Reddington, Dr Claudia Cheng, A/Prof Martin Healey, Dr Keryn Harlow. |
| **Location** | Royal Women’s Hospital Melbourne |

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

**1 Introduction**

You are invited to take part in this research project. This is because you are planning to have surgery at The Royal Women’s Hospital. The research project is testing a new examination measurement which could be linked with the risk of having certain medical conditions, including endometriosis. The examination being tested is called anogenital distance, and is the measurement between the vagina and the anus.

This Participant Information Sheet/Consent Form tells you about the research project and what it involves. 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 examination that is 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?**

In the past, anogenital distance had not been routinely measured during gynaecological examinations. There is new evidence which indicates that women with a shorter anogenital distance are more likely to be diagnosed with endometriosis. Therefore anogenital distance is an experimental aspect of gynaecological examination. This means it must be tested to see if it is an effective means of identifying women who might be at increased risk of conditions such as endometriosis.

This research has been initiated by the study doctor, Dr Thomas Kavanagh

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

If you choose to participate in this study, you will be participating in a cohort study. A cohort study is one which collects data in a set group of participants to compare differences in that group. In this study the researchers are recruiting a group of women who are having gynaecological surgery under general anaesthetic.

After you have read this information, you will be asked to sign a consent form to participate in the study, prior to any of the study assessments being performed.

Step 1 - Questionnaire prior to surgery

* Complete the consent and questionnaire online via survey monkey – this is our

preferred option - OR

* Complete a hard copy of the consent form and questionnaire and return them in a reply

paid envelope.

Some of the questions in the survey are of a sensitive nature and relate to health conditions, previous surgery and previous pregnancies.

All of the responses to this survey are confidential and will only be accessible to researchers involved in this study. Any information about findings from this study will be completely de-identified.

Step 2 - Examination during surgery by gynaecology doctor

During the routine process of any gynaecological surgery the gynaecologists will perform a pelvic examination after you have been anesthetised, and before the beginning of the surgery. If you choose to participate in this study the gynaecologists will measure the anogenital length in addition to their routine examination. The measurement will then be repeated at the conclusion of the surgery, to ensure that measurements are accurate. This measurement may be taken by one gynaecology doctor, or two gynaecology doctors, to ensure that measurements are not different between examiners.

Anogenital distance is measured using a disposable paper ruler. This measurement will be recorded in your electronic medical record.

Two different measurements will be measured and recorded.

- The distance from the front of the vagina (the clitoris) to the anus. This is known as the anterior anogenital distance or AGD AC.

- The distance from the back of the vagina (the posterior fourchette) to the anus. This is known as the posterior anogenital distance or AGD AF.

Your planned surgery will not be affected in any other way by your decision to participate, or not participate, in this study. The gynaecologist will perform the planned surgery as they would normally.

Step 3 - Researchers collect information following surgery

After your surgery is complete there is nothing more you need to do to participate in this study.

Following surgery the researchers will collect the survey responses and anogenital distance measurements. If your surgery is a laparoscopy, they will also review the operation note and pathology reports to see whether endometriosis was diagnosed during the surgery.

This information will then be used to determine what the average anogenital distance is for our study participants, and to examine if there is any relationship between certain conditions and difference in anogenital distance. For example a longer anogenital distance may indicate that endometriosis is more likely to be found at laparoscopy.

There will be no further contact or follow up required from you after your surgery is complete.

It is anticipated that this study will take 24 months to complete data collection, analysis and publication of results.

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.

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

We will invite all women who have a planned or emergency gynaecological surgery performed by the general gynaecology units (Gynaecology Units 1, 2 and Acute Gynaecology Unit) at the Royal Women’s Hospital to take part in this study.

A total of around 250 women will be invited to participate, including around 140 women undergoing laparoscopy.

**5 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 or you can consent online via survey monkey.

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.

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

There will be no direct benefit to you from your participation in this research.

By filling out the questionnaire and allowing your anogenital distance measurements to be recorded we will gain a better understanding of anogenital distance’s significance.

In the future, this may help doctors to better identify women at risk of medical conditions, such as endometriosis.

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

There are no risks or side effects anticipated relating to the measurement of anogenital distance. This measurement should not affect your surgical treatment in any way. The measurements will be recorded by trained staff, experienced in gynaecological examinations.

Your intended surgical procedure has risks associated with it, these will have been discussed previously by the treating doctor booking your procedure. Your participation in this study will not alter those risks.

**8 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 and return the withdrawal of consent form attached to the end of this document.

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.

**9 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:

* Low rate of participants consenting to participate
* Unanticipated side effects or findings

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

After this project has collected enough data, the researchers will analyse the data and publish their findings in a medical journal.

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

**11 What will happen to information about me?**

By signing the consent form or consenting online 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. Confidentiality and privacy will be maintained by giving each woman who

participates a study number, so that her information is de-identified.

All information will be kept secure: all paperwork from the project will be kept in a locked room

and all computerised information will be kept in a database that is password protected. All

information will be kept for a period of 7 years after the project is completed, at which time hard

copy records will be shredded and computer files deleted.

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

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. This will be ensured by providing summarised data or else by referring to individual results by their study number. At no stage will a person’s name or any identifying information be used.

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 Dr Thomas Kavanagh (email

womenshealthresearch@thewomens.org.au or call 03 8345 2000 and leave a message on

pager 53980 for him to call you back) 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.

**12 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 (2007). 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**

If you require further information you may contact the principal researcher, Dr Thomas Kavanagh (email womenshealthresearch@thewomens.org.au or call 03 8345 2000 and leave

a message on pager 53980 for him to call you back).

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 the Royal

Women’s Hospital Consumer Advocate, telephone 8345 2290.

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

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| **Principal Investigator** | Dr Thomas Kavanagh |
| **Associate Investigator(s)** | Dr Charlotte Reddington, Dr Claudia Cheng, A/Prof Martin Healey, Dr Keryn Harlow. |
| **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 give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to The Royal Women’s 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.

* I would like a copy of the result in plain English at the completion of the study

(please tick the box if you would like a copy of the result sent to you and provide an email address to receive the summary\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

**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*

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| **Protocol Number** | Protocol version 0.5 |
| **Principal Investigator** | Dr Thomas Kavanagh |
| **Associate Investigator(s)** | Dr Charlotte Reddington, Dr Claudia Cheng, A/Prof Martin Healey, Dr Keryn Harlow. |
| **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 |  |  |
|  | | | | | | |

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.