Participant Information Sheet/Consent Form

Non-Interventional Study - *Adult providing own consent*

[Insert site name]

Title	*Developing and evaluating a screening tool to improve pre-operative prediction of absence of endometriosis in people with pelvic pain*
Short Title	*Predicting absence of endometriosis*
Protocol Number	66627
Project Sponsor	*The Royal Women's Hospital*
Coordinating Principal Investigator/ Principal Investigator	*Dr Charlotte Reddington*
Associate Investigator(s)	*Dr Samantha Mooney, Dr Uri Dior, Dr Keryn Harlow, Dr Lauren Hicks, Dr Claudia Cheng, Dr Lenore Ellett, Dr Emma Readman, Dr Michal Amir, A/Prof Jim Tsaltas, Melissa Parker, Roshan Karri, Dr Jane Girling, Dr Sarah Holdsworth-Carson, Prof Peter Rogers, A/Prof Martin Healey*
Location	*[Insert Site]*

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, 'Developing and evaluating a screening tool to improve pre-operative prediction of absence of endometriosis in people with pelvic pain'. This is because you have pelvic pain and are planned to have a laparoscopy to see if you have endometriosis. The research project is aiming to make an 'endometriosis calculator' that uses questions about a person's symptoms and medical history and an examination measurement (the anogenital distance – the measurement between the vagina and the anus), to give them a better idea about their chance of having endometriosis before they have an operation.

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?

Pelvic pain is a very common issue. Endometriosis is a common cause of pelvic pain but currently, in most cases, in order to diagnose endometriosis a laparoscopy (key-hole surgery) is needed. While ultrasound can usually pick up endometriosis cysts on ovaries (endometriomas) and larger areas of deep endometriosis, it cannot see superficial (surface) endometriosis which is the most common type. When laparoscopies are undertaken to look for endometriosis in people with pelvic pain, approximately one third will not have endometriosis. That means one third of patients having a laparoscopy for this reason will have put themselves through surgery without the possible benefits.

We plan to make an 'endometriosis calculator' that uses questions about a person's symptoms and medical history and their anogenital distance measurement (distance between the vagina and anus), to give them a better idea about their chance of having endometriosis before they have an operation. This could hopefully be used as a tool that patients could use to help decide if they want to go on and have a laparoscopy or not. It might result in fewer people having unnecessary surgery and getting more appropriate treatment for their pain instead.

This research has been funded by the Australian Government Medical Research Future Fund (MRF9911715 'Improving diagnosis and treatment of endometriosis').

This research is being coordinated by the University of Melbourne Department of Obstetrics and Gynaecology.

3 What does participation in this research involve?

In this study we will look at people already planning to have a laparoscopy for investigation of their pelvic pain. People will be identified as being eligible for this study by the research team members checking the operation waiting lists and the outcomes of clinic appointments in the hospitals that are participating. Eligible participants will be contacted before their planned surgery either in person or over the phone by a member of the research team to ask if they are interested in being involved. People wishing to participate will sign a consent form before any study assessment takes place.

Once they have provided consent participants will fill in a questionnaire (online or in hard copy) about their symptoms and medical history before their operation. The research team will get a copy of the participant's pelvic ultrasound and record the findings.

Participants will then have their surgery as planned. While asleep under the anaesthetic, during the routine examination that takes place before the operation begins, your surgeon will measure your anogenital distance. This is the distance on the outside from the vagina to the anus. This is measured with a clean disposable paper ruler and is not an internal examination. 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.

If endometriosis is seen during the surgery the surgeon will remove it or take a biopsy to have the diagnosis confirmed in the laboratory by a pathologist. Involvement in this study will not change the way the surgery is performed. The surgeon will then complete an operation report and the research team will check the pathology results to confirm if endometriosis was diagnosed.

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 costs associated with participating in this research project, nor will you be paid.

4 What do I have to do?

To participate in this study you need to complete the participant questionnaire before having your surgery. The questionnaire asks about you, your health and medical history and your current symptoms. It takes about 20-25 minutes to complete.

Your surgery will then take place as already planned. There is no follow up required for this study.

5 Other relevant information about the research project

Overall, we plan to have 666 people participate in this study from multiple hospitals in Melbourne, Victoria, Australia and one hospital in Jerusalem, Israel. A member of the research team works as a Gynaecologist in each of the participating hospitals.

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 *[Institution]*.

8 What are the possible benefits of taking part?

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

This research may help people in the future have a better idea about their chance of having endometriosis before they have an operation.

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

The study questionnaire asks some questions of a personal nature. You do not need to answer them if you do not wish to. 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.

For immediate crisis support please contact Lifeline on 13 11 14.

13 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.

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. This is unlikely to occur but may happen if not enough people are interested to participate in the study.

15 What happens when the research project ends?

This research project will take approximately 4 years to complete. After this we will provide participants who are interested a summary of the results via email.

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. Confidentiality and privacy will be maintained by giving each personwho 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. Only members of the research team will have access. 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.

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, *[Name of institution]*, 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. In any publication/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.

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.

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.

If you experience distress as a result of participating in this study please contact the clinical contact listed below in Section 20. For immediate crisis support please contact Lifeline on 13 11 14.

18 Who is organising and funding the research?

This research project is being coordinated by the University of Melbourne Department of Obstetrics and Gynaecology and is funded by the Australian Government Medical Research Future Fund (MRF9911715 'Improving diagnosis and treatment of endometriosis').

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 Austin Health. Site specific approval has also been given by *[Name of institution]*.
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

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 (Dr Charlotte Reddington) on 03 8345 2000 or any of the following people:

CLINICAL CONTACTS *[Delete where appropriate]*

RWH:

Name	Dr Keryn Harlow
Position	Gynaecology 2 Fellow
Telephone	8345 2198
Email	womenshealthresearch@thewomens.org.au

Mercy:

Name	Dr Lauren Hicks
Position	Endosurgery Fellow
Telephone	8458 4444 (via switch)
Email	endosurgeryfellow@mercy.com.au

Epworth Richmond

Name	A/Prof Martin Healey
Position	Consultant gynaecologist
Telephone	95162896
Email	martin@drmartinhealey.net.au

Frances Perry House

Name	Shaune Gillespie
Position	Chief Executive Officer
Telephone	93445000
Email	GillespieShaune@ramsayhealth.com.au

Israel

Name	Dr Uri Dior
Position	Consultant gynaecologist
Telephone	+972 5051 72642
Email	Uri.dior@gmail.com

Western Health/Joan Kirner (Sunshine) Hospital

Name	Dr Samantha Mooney
Position	Obstetrician and Gynaecologist (VMO)

Telephone	0402 923 861
Email	Samantha.mooney@wh.org.au

Epworth Freemasons

Name	A/Prof Kate Stern
Position	Consultant gynaecologist
Telephone	93871000
Email	Kate.stern@mivf.com.au

Warringal Private Hospital

Name	Dr Lenore Ellett
Position	Consultant gynaecologist
Telephone	0401360974
Email	Lenore@crosbie.com.au

St Vincent's Private Hospital

Name	Dr Emma Readman
Position	Consultant gynaecologist
Telephone	0438788854
Email	Ereadman@melbpc.org.au

Holmesglen Private

Name	Dr Michal Amir
Position	Consultant gynaecologist
Telephone	0403274870
Email	Dr.amirmichal@gmail.com

Cabrini Malvern

Name	Dr Michal Amir
Position	Consultant gynaecologist
Telephone	0403274870
Email	Dr.amirmichal@gmail.com

Northpark Private Hospital

Name	Dr Caroline Hoggenmueller
Position	Consultant gynaecologist
Telephone	0410861434
Email	caroline.hoggenmueller@gmail.com

Peninsula Private Hospital

Name	Dr Brett Marshall
Position	Consultant gynaecologist
Telephone	97766411
Email	Brett.Marhsall@thewomens.org.au

Beleura Private Hospital

Name	Dr Brett Marshall
Position	Consultant gynaecologist
Telephone	97766411
Email	Brett.Marhsall@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 CONTACTS *[Delete where appropriate]*

RWH

Name	Royal Women's Hospital Consumer Advocate
Position	Consumer Advocate
Telephone	03 8345 2290
Email	Consumer.liaison@thewomens.org.au

Mercy

Name	Rati Ramnauth
Position	HREC Administrator Mercy Health
Telephone	8458 4808
Email	ethics@mercy.com.au

Epworth

Name	A/Prof Martin Healey
Position	Consultant gynaecologist
Telephone	95162896
Email	martin@drmartinhealey.net.au

Frances Perry House

Name	Tanya Quesnel
Position	Research governance Ramsay Health
Telephone	94333444
Email	QuesnelT@rhrf.org.au

Israel

Name	Hadassah-Hebrew University Medical Center
Position	Helsinki Ethics Committee
Telephone	+972 2 6777111
Email	VHelsinki@hadassah.org.il

Western Health/Joan Kirner (Sunshine) Hospital

Name	Mr Bill Karanatsios
Position	Research Program Director
Telephone	8395 8073
Email	Bill.karanatsios@wh.org.au or ethics@wh.org.au

Warringal Private Hospital

Name	Tanya Quesnel
Position	Research governance Ramsay Health
Telephone	94333444
Email	QuesnelT@rhrf.org.au

St Vincent's Private Hospital

Name	Dr Emma Readman

Position	Consultant gynaecologist
Telephone	0438788854
Email	Ereadman@melbpc.org.au

Holmesglen Private

Name	Dr Michal Amir
Position	Consultant gynaecologist
Telephone	0403274870
Email	Dr.amirmichal@gmail.com

Cabrini Malvern

Name	Dr Michal Amir
Position	Consultant gynaecologist
Telephone	0403274870
Email	Dr.amirmichal@gmail.com

Northpark Private Hospital

Name	Dr Caroline Hoggenmueller
Position	Consultant gynaecologist
Telephone	94677024
Email	info@born-group.com.au

Peninsula Private Hospital

Name	Tanya Quesnel
Position	Research governance Ramsay Health
Telephone	94333444
Email	QuesnelT@rhrf.org.au

Beleura Private Hospital

Name	Tanya Quesnel
Position	Research governance Ramsay Health
Telephone	94333444
Email	QuesnelT@rhrf.org.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	Austin Health Human Research Ethics Committee
HREC Executive Officer	Ms Lisa Pedro
Telephone	03 9496 4090
Email	ethics@austin.org.au

Consent Form - *Adult providing own consent*

Title	*Developing and evaluating a screening tool to improve pre-operative prediction of absence of endometriosis in people with pelvic pain*
Short Title	*Predicting absence of endometriosis*
Protocol Number	66627
Project Sponsor	*The Royal Women's Hospital*
Coordinating Principal Investigator/ Principal Investigator	*Dr Charlotte Reddington*
Associate Investigator(s)	*Dr Samantha Mooney, Dr Uri Dior, Dr Keryn Harlow, Dr Lauren Hicks, Dr Claudia Cheng, Dr Lenore Ellett, Dr Emma Readman, Dr Michal Amir, A/Prof Jim Tsaltas, Melissa Parker, Roshan Karri, Dr Jane Girling, Dr Sarah Holdsworth-Carson, Prof Peter Rogers, A/Prof Martin Healey*
Location	*[Insert Site]*

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.

- ☐ I agree to be contacted by the research team about my participation in future ethically approved research projects
- ☐ I wish to receive a copy of the results at the conclusion of this study in non-technical language

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

Declaration - for participants unable to read the information and consent form
See Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 Section 4.8.9. A legally acceptable representative may be a witness*.
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. 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	*Developing and evaluating a screening tool to improve pre-operative prediction of absence of endometriosis in people with pelvic pain*
Short Title	*Predicting absence of endometriosis*
Protocol Number	66627
Project Sponsor	*The Royal Women's Hospital*
Coordinating Principal Investigator/ Principal Investigator	*Dr Charlotte Reddington*
Associate Investigator(s)	*Dr Samantha Mooney, Dr Uri Dior, Dr Keryn Harlow, Dr Lauren Hicks, Dr Claudia Cheng, Dr Lenore Ellett, Dr Emma Readman, Dr Michal Amir, A/Prof Jim Tsaltas, Melissa Parker, Roshan Karri, Dr Jane Girling, Dr Sarah Holdsworth-Carson, Prof Peter Rogers, A/Prof Martin Healey*
Location	*[Insert Site]*

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 *[Institution]*.

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.