IMAGENDO

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ROBINSON RESEARCH INSTITUTE
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**PARTICIPANT INFORMATION SHEET**

**PROJECT TITLE: Non-invasive endometriosis diagnosis using machine learning (Stage 2)**
**HUMAN RESEARCH ETHICS COMMITTEE APPROVAL NUMBER: H-2020-051**
**PRINCIPAL INVESTIGATOR: A/Prof Louise Hull**

Dear Participant,
You are invited to participate in the research project described below.

**What is the project about?**
This research project is about improving the ability to diagnose endometriosis without surgery. Women with endometriosis have tissue lesions similar to endometrial tissue (the tissue that lines the womb and is shed during menstruation) growing outside the womb within the pelvic cavity. Currently, the only reliable way of diagnosing endometriosis is to perform keyhole surgery and visualise the endometrial deposits inside the abdomen. Because surgery is risky and expensive, researchers have sought to find other non-invasive ways to diagnose endometriosis. Although not perfect, the two most accurate tests were identifying endometriosis lesions using endometriosis-specific ultrasound scans and MRI (magnetic resonance imaging). These two tests provide different information and we hope to combine the digital information from both tests using computer algorithms (machine learning) to improve the ability to diagnose endometriosis without surgery.

**Who is undertaking the project?**
This project is being conducted by a group of researchers from The University of Adelaide, Bensons Radiology, Specialist Imaging Partners and the University of Sydney, including

A/ Prof Louise Hull, *The University of Adelaide*
Prof Gustavo Carneiro, *The University of Adelaide*
Ms Catrina Panuccio, *Specialist Imaging Partners*
Dr Jane Woolcock *The University of Adelaide*
A/Prof George Condous, *University of Sydney*
Dr Frank Voyvodic, *Benson Radiology*
Dr Steven Knox, *Benson Radiology*
Dr Melissa Jenkins, *Benson Radiology*
Dr Gabriel Maicas, *The University of Adelaide*
Dr Jodie Avery, *The University of Adelaide*

**Why am I being invited to participate?**
You are being invited as you have been placed on a surgical waiting list for surgery as for suspected endometriosis. This study aims to recruit women who have had or are willing to undertake a transvaginal endometriosis scan and an MRI before surgery. You have to be between 18 and 45 to participate.

**What am I being invited to do?**
You are being invited to have a transvaginal ultrasound and an MRI scan for diagnosing endometriosis before having your surgery. Many surgeons currently use either of these tests as part of their preoperative assessment, however in this study you would need to have both. The study is not blinded, and you and your doctor will be able to access the results and use them as part of your treatment plan. If you have already had a transvaginal ultrasound and /or an MRI scan for diagnosing endometriosis, we will ask your permission to obtain a copy of the scans for our research. Additionally, some questions about your symptoms and the outcome of your surgery will be recorded by the researchers.

**How much time will my involvement in the project take?**
Your ultrasound scan and Magnetic Resonance Imaging scan will take in total approximately 2 hours to perform. Your follow up appointment with the gynaecologist about your results will take 1 hour. Completing the Redcap questionnaire (**https://is.gd/imagendostudy**) will take you 5 minutes, and completing an MRI questionnaire will also take 5 minutes. **(bensonradiology.com.au/mrisafety)**

**Are there any risks associated with participating in this project?**
Both MRI and ultrasound are standard investigative tests with very few risks or side effects. A transvaginal scan may incur mild discomfort. There is a brief exposure to a magnetic field when an MRI is undertaken.

**What are the potential benefits of the research project?**
We may find information on the ultrasound or MRI scans that will help your surgeon better plan your surgery. However, we cannot guarantee that taking part in the trial will be of direct benefit to you. This research aims to further medical knowledge and enable new pathways to investigate and diagnose endometriosis which may help other women in the future.
You will not be paid for participation in this study and nor will you incur any financial cost. No individual researcher will gain direct financial benefit from conducting the study.

**Can I withdraw from the project?**
Participation in this project is completely voluntary. If you agree to participate, you can withdraw from the study up until a month after the follow-up consult with the gynaecologist after your surgery. However, it will not be possible to withdraw once analysis of the study results has begun or have been published.

**What will happen to my information?**
Your information will only be used as described in this participant information sheet and it will only be disclosed according to the consent provided, except as required by law.

*Confidentiality and privacy:*
Nursing and medical staff involved in your care will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will not be disclosed without your permission, except as required by law.

All data and images will be given a non-identifying code to protect your anonymity. Only clinically qualified (nurses and doctors) members of the research team will be able to access clinical information. All non-clinical research members (bioinformaticians, statisticians etc) will only receive coded anonymous information pertaining to their role in the project. Consent forms will be kept in a locked file separate to the anonymized, coded clinical information and samples.
Your health record, medical notes and any information obtained during the study may be examined by authorized representatives of the hospital's Human Research Ethics Committee, staff from the NHMRC Clinical Trials Centre and by regulatory authorities as required by law, for the purposed of verifying the study procedures or data.
Your personal results will be conveyed to you by your doctor before or in relation to your surgical procedure. You may bring a family member or friend with you to all appointments.
*Publishing:* We plan to discuss/publish the results from the overall trial in peer-reviewed journals, presentation at conferences or other professional forums in such a way that you cannot be identified. The trial outcomes can be provided to you, if you wish, by your study doctor.

*Storage*: The images will contribute to your medical records and will be held on file in your notes and at the imaging centres who undertook the test as is standard clinical care. Anonymised and coded MRI and ultrasound images and some of your health information may be put into a database but will not contain identifying data such as your name or address. We take many steps to protect your privacy but there is still a small chance that someone could trace information back to you. Your information will only be used as described in this participant information sheet and it will only be disclosed according to the consent provided, except as required by law.

The ultrasound and MRI files will be stored until the researcher's investigations are complete, for a minimum of five years from the date of publication of any reports or papers. The Ultrasound and MRI files will be kept in password protected file in the researcher's computer in the School of Computer Sciences, separate from the identification key. Additionally, any personal details that have been provided with consent for the ongoing register will be stored and maintained for a minimum of 5 years in a password protected file in the researcher's computer at the Adelaide Medical School.

**Who do I contact if I have questions about the project?**

If you require further information you can contact the Principal Investigators or study staff.
The Investigators responsible for the study are:

1) Dr Jodie Avery, Researcher, University of Adelaide 0450 534 950 or **endostudy@adelaide.edu.au**
2) Associate Professor Louise Hull, Research Program Leader, Endometriosis Research Group, Discipline of Obstetrics and Gynaecology, Robinson Research Institute, AHMS Building on 1300 848 470 or 0403933312

**What if I have a complaint or any concerns?**

The study has been approved by the Human Research Ethics Committee at the University of Adelaide (approval number H-2020-051). This research project will be conducted according to the NHMRC National Statement on Ethical Conduct in Human Research 2007 (Updated 2018). If you have questions or problems associated with the practical aspects of your participation in the project, or wish to raise a concern or complaint about the project, then you should consult the Principal Investigator.

If you wish to speak with an independent person regarding concerns or a complaint, the University's policy on research involving human participants, or your rights as a participant, please contact the:

Human Research Ethics Committee's Secretariat on:
Phone: +61 8 8313 6028
Email: hrec@adelaide.edu.au
Post: Level 4, Rundle Mall Plaza, 50 Rundle Mall, ADELAIDE SA 5000

Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

**If I want to participate, what do I do?**

Thank you for taking the time to consider being part of this study. If you wish to take part in this study please sign the attached consent form and return to the drop box at reception or mail to us in the reply paid envelope provided.

Yours sincerely,

A/ Prof Louise Hull, *The University of Adelaide*
Prof Gustavo Carneiro, *The University of Adelaide*
Ms Catrina Panuccio, *Specialist Imaging Partners*
Dr Jane Woolcock *The University of Adelaide*
A/Prof George Condous, *University of Sydney*
Dr Frank Voyvodic, *Benson Radiology*
Dr Steven Knox, *Benson Radiology*
Dr Melissa Jenkins, *Benson Radiology*
Dr Gabriel Maicas, *The University of Adelaide*
Dr Jodie Avery, *The University of Adelaide*

**Human Research Ethics Committee (HREC)**

# CONSENT FORM

1. I have read the attached Information Sheet and agree to take part in the following research project:

| | |
|---|---|
| **Title:** | Non-invasive endometriosis diagnosis using machine learning (Stage 2) |
| **Ethics Approval Number:** | H-2020-051 |

2. I have had the project, so far as it affects me, and the potential risks and burdens fully explained to my satisfaction by the research worker. I have had the opportunity to ask any questions I may have about the project and my participation. My consent is given freely.

3. I have been given the opportunity to have a member of my family or a friend present while the project was explained to me.

4. Although I understand the purpose of the research project is to improve the quality of health/ medical care, it has also been explained that my involvement may not be of any benefit to me.

5. I agree to participate in the activities as outlined in the participant information sheet.

6. I understand that I am free to withdraw from the project until a month after I have agreed to provide access to my MRI or TV-US scan, and that this will not affect medical advice in the management of my health, now or in the future.

7. I have been informed that the information gained in the project may be published in a book/ journal article / news article/ conference presentations/ website/ report.

8. I have been informed that in the published materials I will not be identified, and my personal results will not be divulged.

9. I agree to my information being used for future research purposes as follows:
   - Research undertaken by these same researcher(s) Yes ☐ No ☐
   - Related research undertaken by any researcher(s) Yes ☐ No ☐
   - Any research undertaken by any researcher(s) Yes ☐ No ☐

10. I have had a Magnetic Resonance Imaging Scan or a Transvaginal Ultrasound Scan and I give permission for the researchers to access these from the diagnostic Imaging practice.

11. I understand my information will only be disclosed according to the consent provided, except where disclosure is required by law.

12. I am aware that I should keep a copy of this Consent Form, when completed, and the attached Information Sheet.

**Participant to complete:**

Name: _____ Signature:_____

Date: _____

**Researcher/Witness to complete:**

I have described the nature of the research to: _____
*(print name of participant)*

and in my opinion, she understood the explanation. Signature: ----------

Position: ..... Date:----------