Participant Information Sheet/Consent Form

Non-Interventional Study - *Adult providing own consent*

Title	National Endometriosis Clinical and Scientific Trials (NECST) Registry
Short Title	NECST Registry
Protocol Number	62508
Project Sponsor	Jean Hailes for Women's Health
Coordinating Principal Investigator	Professor Jason Abbott
Associate Investigator(s)	
Location	

Your participation is voluntary

Your participation in this study is completely voluntary and there will be no cost to you. If you do not want to take part in this study, you do not have to. You should feel under no obligation to participate in this study. Choosing not to take part in this study will not affect your current and future medical care in any way.

Your withdrawal from the study

You are under no obligation to continue with the research study. You may change your mind at any time about participating in the research. People withdraw from studies for various reasons and you do not need to provide a reason. You can withdraw from the study at any time by completing and signing the '**Participant Withdrawal of Consent Form**'. This form is provided at the end of this document and is to be completed by you and supplied to the research team if you choose to withdraw at a later date. If you withdraw from the study, you will be able to choose whether the study will **destroy** or **retain** the information it has collected about you. You should only choose **one** of these options. Where both boxes are ticked in error or neither box is ticked, the study will **destroy** all information it has collected about you.

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project that is establishing the National Endometriosis Clinical and Scientific Trials (NECST) Registry. Endometriosis is a benign (non-cancerous) gynaecological condition that affects about 10% of reproductive aged women. The cause of endometriosis is unclear and at present, diagnosis is only possible with surgery. Adenomyosis, described as endometriosis in the muscle of the uterus, is also common, can occur alongside endometriosis and its causes and optimal treatments are likewise not well understood. You have been invited to participate because you are being investigated due to symptoms possibly relating to endometriosis or adenomyosis (e.g. persistent pelvic pains, problems with fertility, abnormal uterine bleeding, etc.), have been diagnosed with endometriosis and/or adenomyosis already by surgery or are being managed with symptoms relating to endometriosis and/or adenomyosis and being managed non-surgically. The project is

aiming to establish the NECST Registry to facilitate high quality research that will improve the diagnosis, treatment and prognosis for people diagnosed with endometriosis and adenomyosis.

This Participant Information Sheet/Consent Form tells you about the research project. It explains what is involved if you decide to take part in the Registry. 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.

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 Registry – you can choose which parts you do or do not consent to
• 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.

Your treating clinician will also confirm your consent with you in person at your next appointment and you will be given opportunity to ask questions or if you would like to know more.

2 What is the purpose of this research?

The project is part of a National collaborative project by Australian clinicians and researchers - the National Endometriosis Clinical and Scientific Trials (NECST) Network, coordinated by Jean Hailes for Women's Health. This research has been funded by the Australian Federal Government's Medical Research Future Fund.

The NECST Registry will be a national resource of participant data that will facilitate high quality research aiming to understand the causes of endometriosis, improve diagnosis and treatment outcomes, and reduce the burden of disease for patients with endometriosis-related symptoms or diagnosed with endometriosis (including adenomyosis). Currently, there is a lack of clinical data about endometriosis and adenomyosis. This is why there can be a substantive delay before a diagnosis of endometriosis or adenomyosis is made for some people. In addition, clear pathways for care are not yet available due to the lack of understanding of how endometriosis or adenomyosis develops and changes during a woman's lifetime.

The NECST Registry will collect and securely store demographic and health related information from consenting participants, who experience and/or seek management for endometriosis and/or endometriosis – and related symptoms (including adenomyosis).

The data collected will be made available to approved researchers undertaking endometriosis-related research (including adenomyosis).

3 What does participation in this research involve?

If you agree to participate in this study, you will be asked to sign the Participant Consent Form. With your permission (consent), your clinician will add your data into the NECST Registry.

Data collection into the NECST Registry will occur in two ways:
i) Through you, via a weblink to a questionnaire that will ask:
    a. General information, such as your name, date of birth, place of birth, residential address, contact details, education and employment.
    b. Medical history of your presenting symptoms, duration of your symptoms, previous diagnoses and/or pregnancies and clinical care.
    c. Questionnaire to understand impact of your symptoms on quality of life.

d. Questionnaire to understand impact of environmental and lifestyle factors on diagnosis.

With your consent, once you are enrolled on the Registry, we will contact you by email or post to complete updates of your history and to consider completing further surveys. This will occur at 6 months after enrolment, at 12 months and then each year thereafter. We will analyse the data that you provide without identifying you and this will provide information for a report describing the participants on the Registry (e.g. age range, how many participants).

ii) Through your doctor, who will add other details directly onto the Registry such as:
   a. Your endometriosis diagnosis (including adenomyosis) and treatment details (and any adverse effects of treatment)
   b. The results of any ultrasound or MRI scans to either detect or assess the severity of endometriosis (including adenomyosis).
   c. The results of any tests to confirm if you had endometriosis and/or adenomyosis.

You can request a copy of the information you or your doctor has entered for your own medical record.

In addition, if you consent to do so, details of any samples of tissue that are collected during any surgical care (as required for the diagnosis of endometriosis and/or adenomyosis) will be documented on the Registry. Collection of these tissues is NOT part of this Registry or consent, but we would like your permission to record if they are taken as this may help future research studies. Your doctor will discuss with you and take a separate consent for tissue sample collection and banking (called 'biobanking') before your procedure.

You will be also be asked to consider a consent form authorising NECST Registry access to your Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) data. Medicare collects information on your doctor visits and the associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies. The consent form is sent securely to Services Australia who holds this information confidentially and would only provide it to researchers if you allow them to do so.

We will also ask if you consent for the Registry to confidentially and securely provide your details to approved researchers who have an ethically and scientifically approved research study around endometriosis. These researchers may contact you about whether or not you would like to participate in future studies. You are not obliged to do so and may decline any or all such invitations. These studies may include researchers who link together your medical information such as from Medicare and prescriptions dispensed and include clinical information. Such 'linkage' studies collect information without specifically identifying you individually and may provide important information on treatments and outcomes for endometriosis. Any future related studies requesting access to your MBS/PBS data will require approval from Services Australia and your consent.

Bias
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. This is one of the reasons we ask general questions about you in the surveys – so we can take into account the background and medical history of the range of participants in the study when we interpret research based on the data in the Registry.

Additional costs & reimbursement
There are no costs associated with participating in this research project, nor will you be paid for your involvement in the NECST Registry.

4 What do I have to do?

Your treatment and care will not alter as a result of participating in this project. You should continue with any medication according to your doctor's advice and don't need to change any lifestyle or dietary choices to participate.

As mentioned above, you will be required to enter general information, medical history information and answer a questionnaire on the impact of endometriosis on your quality of life. In addition, the NECST Registry aims to assess the long-term impact and life course of endometriosis symptoms and diagnosis. We will be sending out regular questionnaires relating to impact on quality of life. You may be required to answer two questionnaires, one for everyone and another more specific questionnaire if you are diagnosed with endometriosis.

You will be contacted (via the method of your choice) to complete these questionnaires at 6 months, 12 months and annually, from the time of your initial consultation with your doctor.

5 Other relevant information about the research project

The NECST Registry is a collaboration involving many clinicians and researchers across Australia who are part of the NECST Network, collecting data on participants.

Studies using the NECST Registry data may generate future research studies. We would be very grateful for your willingness to take part in them. If you consent for the Registry to provide your details to approved researchers to invite you to participate in such future studies another consent form specific for the new study will need to be completed by you.

6 What are the possible benefits of taking part?

The major benefit of the NECST Registry is to improve research into the diagnosis, management and treatment for women who may be diagnosed with endometriosis (including adenomyosis) in the future. You will have a copy of your medical information that you can take to any future medical carer for your endometriosis and many clinicians across the country will be participating in the Registry. However, there may be no other direct benefit to you from your participation in this research.

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

There are no risks to your health by having your details stored on the NECST Registry.

The main disadvantages of participation relate to inconvenience and time taken to complete the participant registration, medical history and follow up questionnaires as described above.

If you become upset or distressed as a result of your participation in the research, the study team 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.

8 Could this research project be stopped unexpectedly?

This research project is a prospective collection of participant clinical data for future research. It is unlikely that early termination would be required since there is no direct intervention, however, possible circumstances that may call for the early termination of this study include changes in the investigator team due to unforeseen circumstances or insufficient funding is provided to continue ongoing maintenance of the NECST Registry.

9 What happens when the research project ends?

This research project is for the establishment of a national Registry designed to be maintained into the foreseeable future. We will notify you if it ever becomes necessary to close the Registry.

Participants enrolled on the Registry will receive communications by email and/or post at regular intervals which will keep you updated with the activities of the Registry including results of research.

Part 2 How is the research project being conducted?

10 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. Of the people treating you, only _____ and their immediate 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, be used for the purpose of this research project and will be disclosed only with your permission, or except as required by law. Only the researchers and clinicians involved in your usual care will have access to your details and results that will be held securely on behalf of the NECST Network.

Information about you may be obtained from your health records held at this health services for the purpose of this research. By signing the relevant section of the consent form, you agree to the research team accessing health records if they are relevant to your participation in this research project. If you do not consent to this, your records will not be accessed.

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. All privacy measures have been put in place to ensure that the confidentiality of your personal and health information are maintained, including removal of identifying information, the use of unique study numbers and adherence to strict guidelines regarding data transfer, storage and access.

In accordance with relevant Australian and/or your State/Territory 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.

Your details and results are held securely by VCS Foundation Ltd, who manage the secure data platform that hosts the Registry. Your data will be stored in a for-purpose registry platform configured and managed by VCS Foundation to support the NECST Network Registry using an existing proven digital health management system. The data are stored securely in Microsoft Azure in the cloud with access only available to authorised users. For the linking of your health information to MBS and PBS information, there is a small risk to your privacy because personal information is used in the record linkage process. This risk is minimised by separating the processes of record linkage and data analysis, with only registry staff and data linkage unit staff accessing separated identifying details and researchers only receiving de-identified data. The record linkage only uses personal information such as name, date of birth, and home address. At the time of linkage, a unique personal identification number will replace your personal information.

11 Complaints and compensation

Complaints

This study has been approved by Monash Health Human Research Ethics Committee (HREC). Any person with concerns or complaints about the conduct of this study should contact the Research Support Office which is nominated to receive complaints from research participants. Their contact details are listed below and quote protocol number 62508.

Treatment available

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.

Compensation

In the event of loss or injury, the parties involved in this research project have agreed to in accordance with Medicines Australia Indemnity and Compensation Guidelines.

12 Who is organising and funding the research?

This research project is being conducted by Jean Hailes for Women's Health using funding awarded by the Australia Government's Medical Research Future Fund.

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

13 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 *Monash Health*.

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.

14 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, you can contact the principal study doctor on _____ or any of the following people:

Clinical contact person

Name	
Position	
Telephone	
Email	

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

Name	*Dr Cecilia Ng*
Position	*Clinical Trials Network Manager*
Telephone	*+61 416 807 183*
Email	*cecilia.ng@jeanhailes.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	*Monash Health*
HREC Executive Officer	*Ms Deborah Dell*
Telephone	*03 9594 4611*
Email	*research@monashhealth.org*

Local HREC Office contact (Single Site - Research Governance Officer)

Name	*Mr Michael Kios*
Position	*Research Governance Manager*
Telephone	*03 9594 4606*
Email	*michael.kios@monashhealth.org*

Services Australia contact

If you have a privacy complaint in relation to the use of your MBS/PBS data, you should contact the Office of the Australia Information Commissioner. You will be able to lodge a complaint with them.

Website	www.oaic.gov.au
Telephone	1300 363 992
Email	enquiries@oaic.gov.au
Mail	GPO Box 5218, Sydney NSW 2001