Participant Information Sheet/Consent Form

The Royal Women's Hospital

Title	The impact of age and parity on the experience of relief and regret in women who have undergone hysterectomy for benign disease.
Principal Investigator	Dr Charlotte Reddington
Associate Investigator(s)	Dr Uri Dior, Dr Claudia Cheng, A/Prof Lesley Stafford, A/Prof Martin Healey

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, "The impact of age and parity (how many children you have had) on the experience of relief and regret in women who have undergone hysterectomy for benign (non-cancer) disease." You are invited to take part because you underwent a hysterectomy at the Royal Women's Hospital. There is very little scientific data about women's experience after hysterectomy so you are in a unique position to share this very important information. We hope the results of this project will be useful to guide discussions between doctors and future patients who might be considering a hysterectomy.

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 in the future at the Royal Women's Hospital 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 research that is described
• Consent to the use of your personal and health information as described.

2 What is the purpose of this research?

The decision to undergo hysterectomy (removal of the uterus/womb) for benign (non-cancerous) conditions can be difficult for both the treating clinician and the woman involved. There are no scientific studies that describe what factors (such as age, pregnancy history and medical conditions) affect the experience of relief and/or regret following hysterectomy for benign conditions such as endometriosis (when cells that normally grow in the lining of the uterus grow

outside of it), adenomyosis (where cells that normally grow in the lining of the uterus grow in the muscle layer of the uterus), fibroids (non-cancerous growths of the uterus) or prolapse (pelvic organs bulging or sagging into the vagina). We are interested in how and why women make the decision to undergo hysterectomy, how it changes their quality of life and experience of symptoms, if at all, and whether it is associated with significant relief or regret. This information will help guide women and their clinicians considering hysterectomy as an option.

3 What does participation in this research involve?

To participate in this research you need to do the following:

- Complete the consent and questionnaire online via survey monkey https://www.surveymonkey.com/r/RWHwomenshealthstudy OR
- Complete a hard copy of the consent form and questionnaire and return them in a reply paid envelope.

The questionnaire asks about your background, symptoms and quality of life before and after your hysterectomy and reflections on your experience of having a hysterectomy and about your current psychological and general well-being.

The questionnaire will take approximately 20 minutes to complete. If completed in hard copy, you can return the questionnaire via post in the reply paid envelope provided.

All the results of the questionnaires will be analysed at the end of the study. All information is kept confidential and stored securely at all times.

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 Other relevant information about the research project

We have invited all women who had a planned (non-emergency) hysterectomy for benign (non-cancerous) conditions performed by the general gynaecology units (Gynaecology Units 1, 2 and 3) at the Royal Women's Hospital between 1st January 2008 and 31st July 2015 (inclusive) to take part in this study. This means that about 1250 women have been invited to participate, including approximately 110 women aged under 36 years at the time of their hysterectomy.

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 there are some questions in the questionnaire(s) you prefer not to answer you can leave them blank. 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 questionnaires we will gain a better understanding of women's experience following hysterectomy. In the future, this may help doctors to better counsel women considering hysterectomy and will help patients make a more informed decision regarding their treatment.

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

If you become upset or distressed as a result of your participation in the research, a 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. If we identify from the responses in your questionnaire that you are experiencing high levels of stress, anxiety or depression or you indicate you would like support regarding an experience of abuse or assault, a study doctor will contact you to discuss arranging support or referral, if you would like. Please note that it may take several weeks from us receiving your response to you being contacted. If you have any concerns we encourage you to directly contact the study doctor, Dr Charlotte Reddington by email: womenshealthresearch@thewomens.org.au or calling 83452000 and leaving a message on pager 52029 for her to call you back. For immediate crisis support please contact Lifeline on 13 11 14.

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.

9 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include a low reply rate from invited participants.

Part 2 How is the research project being conducted?

10 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 5 years after the project is completed, at which time hard copy records will be shredded and computer files deleted.

SurveyMonkey is an online cloud based platform. They do not have permission to access your personal information or responses. The security of the SurveyMonkey system however cannot be guaranteed by the research team.

In any publication, 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.

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.

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 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 Charlotte Reddington (email womenshealthresearch@thewomens.org.au or call 03 8345 2000 and leave a message on pager 52029 for her 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.

11 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.

12 Further information and who to contact

If you require further information you may contact the principal researcher, Dr Charlotte Reddington (email womenshealthresearch@thewomens.org.au or call 03 8345 2000 and leave a message on pager 52029 for her 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

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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 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 _____)
- ☐ I consent to being contacted in the future with a view to participating in an interview

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Doctor/Senior Researcher†

I have provided written explanation of the research project, its procedures and risks and given the participant opportunity to contact me for further information.

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.

Refusal of Consent Form

Title	The impact of age and parity on the experience of relief and regret in women who have undergone hysterectomy for benign disease.
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I do **not** wish to participate in the above research project

I understand that my decision not to participate will not affect my routine treatment, my relationship with those treating me or my relationship with The Royal Women's Hospital.

I understand by returning this refusal of consent form I will not be contacted again regarding this research project.

Name of Participant (please print) _____

Signature _____ Date _____

Form for Withdrawal of Participation

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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.

Research data already collected on me will be deleted/destroyed in a confidential manner.

Name of Participant (please print) _____

Signature _____ Date _____