Participant Information Sheet/Consent Form

Non-Interventional Study - *Adult providing own consent*

Title	Constipation after elective laparoscopy for benign gynaecological indications – a prospective observational study
Protocol Number	
Principal Investigator	Dr Paul Berlund
Associate Investigator(s)	Dr Charlotte Reddington A/Prof Martin Healey Dr Claudia Cheng
Location	The Royal Womens Hospital Parkville, Melbourne. Victoria

Part 1 What does my participation involve?

1. Introduction

You are invited to take part in this research project because you are planned to undergo a laparoscopic procedure at The Royal Womens Hospital. The research project is aiming to assess the impact that laparoscopic surgery has on a person's bowel function, leading to constipation. It is currently not known how common constipation is after laparoscopy for gynaecological conditions and to what extent this leads to bother, distress, or discomfort. Your participation in this study will help define this and help us to better manage our patients in the future.

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?

The aim of this study is to discover how common constipation and altered bowel habit is after laparoscopy for gynaecological problems. We know that having surgery or using pain killers after surgery is likely to lead to constipation, but no studies have been performed to find out how common constipation is or if this is a distressing problem for people who have had surgery.
By performing this research, we hope to better manage our patients who are having laparoscopic surgery .

3. What does participation in this research involve?

The research involves completing three questionnaires related to your surgery at The Royal Women's Hospital. These questionnaires will take less than ten minutes to complete.

The first step is completing this consent form. No part of the study will be performed without the consent of the participants.

After your consent is obtained your treating doctor will determine if you are eligible to participate in the trial. People who have certain pre-existing conditions, such as a chronic bowel disorder, or patients undergoing certain procedures will not be eligible to participate.

If you are considered eligible to participate in the trial you will be asked to complete three questionnaires. The first questionnaire will be performed prior to your surgery being performed. The second questionnaire will be performed in the second week after your operation. The third questionnaire will take place three months after your operation.

The questionnaires can be completed using your personal electronic device via the "Survey Monkey" service (a link will be messaged to you to complete) or if you prefer on paper. The questionnaires will detail information about your health, your bowel habit, and you intake of pain killers and laxative before, during and after your procedure.

Your treating doctor will complete a form that will detail the type of surgery that has been performed, the extent of any endometriosis if present, the use of pain killers during your hospital stay and if any complications occurred. Your treatment will not be altered in any way by decision to participate in this research project.

We plan to have 100 people complete these questionnaires and the project will expect to run over a period of six months.

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?

Participation in this study involves you completing the three questionnaires during your surgical journey. We ask that you take the advice of your treating doctor with regards to any instructions regarding care after your surgery. This study does not require you to have any restrictions on diet and medications, but you should follow other restrictions, if any, from your treating doctor. If you are having difficulties with regards to constipation or any other aspect of your recovery, we recommend you seek advice from your treating doctor, your general practitioner or attend the women's emergency centre.

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.

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 Womens Hospital

6. What are the possible benefits of taking part?

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

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

This research does not involve any interventional treatment, as such there are no additional risks or side effects from participating in this project.

You have been invited to participate in this study as you are planned to undergo surgery. Surgery itself is associated with risks as is undergoing general anaesthesia. The medications given to you during or after your procedure may also have side effects.

If you are concerned about your surgery or other aspects of your care please discuss this with your treating doctor

8. What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

9. Can I have other treatments during this research project?

This Study does not require you to have any restrictions on other treatments, but you should follow the restrictions, if any, from your treating doctor.

10. 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 before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing.

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 research team up to the time you withdraw will form part of the research project results.

11. Could this research project be stopped unexpectedly?

There is no foreseeable reason that that this research project would be stopped unexpectantly. However, this research project may be stopped unexpectedly for a variety of reasons. These may include if other studies are performed yielding new information or if new treatments become available

12. What happens when the research project ends?

After the completion of the project the information will be gathered and analysed. The results of this project may be presented at scientific meetings or published in a medical journal. The results of this study may lead to the development of new guidelines for treating patients in the future.

A summary of the results of the project will be made available to all participants at the completion of the study. This can be requested by email to the principal investigator.

Part 2 How is the research project being conducted?

13. 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. Upon enrolment in the study you will be assigned a study number and information collected will only be expressed based on this number. . 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 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 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.

14. Complaints and compensation

If you have any problems 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.

15. Who is organising and funding the research?

This research project is being conducted by Dr Paul Berlund. Dr Berlund has not obtained any funding for the completion of this project

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

16. 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 Womens 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.

17. 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 on 03 8345 2000 or any of the following people:

Clinical contact person

Name	Paul Berlund
Position	Lead clinical investigator
Telephone	03 8345 2000
Email	paul.berlund@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 contact person

Name	The Royal Womens Hospital Consumer Advocate
Telephone	03 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 signed copy of this document to keep.

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

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.

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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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 Womens Hospital

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.