Health
Western Sydney
Local Health District

INFORMED PATIENT CONSENT FORM

Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Title	LigaSure Retractable L-Hook compared with Harmonic Ace +7 as a single instrument for total laparoscopic hysterectomy: Is bipolar energy superior to ultrasonic energy? A randomised controlled trial
Short Title	LigaSure L-Hook Vs Harmonic Ace +7 for total laparoscopic hysterectomy
Protocol Number	1
Project Sponsor	Nil
Coordinating Principal Investigator/ Principal Investigator	Dr Clare Wong
Associate Investigator(s)	Bassem Gerges, George Hardas, Imad Mahmoud, Harry Merkur, Yogesh Nikam, Luice Wang, Clare Wong, Amy Feng, Basia Slusarczyk
Location	**Blacktown Hospital**

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you are having a hysterectomy for your gynaecological condition. The research project is to compare the operative time and blood loss of two pieces of laparoscopic equipment. They are called LigaSure Retractable L-Hook (LigaSure) and Harmonic ACE +7 (Harmonic).

This Participant Information Sheet/Consent Form tells you about the research project. It explains what will be 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 your 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 have the tests and treatments 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?

This study is to compare the surgical outcomes (operative time, blood loss and complications) of two very similar pieces of laparoscopic equipment: LigaSure and Harmonic. The instruments differ by the type of energy that is used – one is a bipolar energy source and one is an ultrasonic energy source. They both seal and cut vessels and are both routinely used for laparoscopic hysterectomy. We want to determine if one device results in a shorter operating time than the other, or if they are the same. At the moment, it is believed they take the same amount of time.

LigaSure and Harmonic are all government regulatory body approved laparoscopic devices used in standard hospital care. They have been widely used in laparoscopic surgery for hysterectomies for several years. The safety of these two instruments has been well established in clinical practice.

This research has been initiated by the study doctors, Dr Amy Feng and Dr Clare Wong.

3 What does participation in this research involve?

If you have been scheduled for a total laparoscopic hysterectomy (without any other planned concurrent surgery) for a benign (non-cancerous) reason where the ultrasound shows a uterus smaller than 14 weeks size and you have a body mass index less than 40, you will be invited to participate in our study.

If you agree to participate in this study, you will be asked to sign a Participant Consent Form before you are enrolled in the study.

As a participant, you will be randomized into one of two groups. You will receive either the LigaSure Retractable L Hook or the Harmonic Ace +7 to perform the hysterectomy. The surgery will be performed in the same routine manner as if you were not in a trial. The surgeon is allowed to use another instrument to seal or cut vessels if they need to.

There are no extra tests, visits, or additional tissue sample involved. Your medical record will be accessed to obtain information about your general health and any previous operations. Information related to your procedure, such as the operating time, blood loss, complications, readmissions will be collected both during your procedure and up to 6 weeks after the procedure. The histopathology from your hysterectomy will be collected. However, the care provided to you during and after your participation in the trial will not be any different to as if you were not in the trial.

You will be followed up 6 weeks after the surgery as a routine postoperative follow-up. Your involvement will be for 6 weeks (from day of surgery to final follow-up). The duration of the entire project is predicted to be three years.

This trial will be monitored by the Western Sydney Local Health District ethics committee as well as an independent data monitoring committee. This Independent data monitoring committee consists of three clinicians experienced in research and familiar with the planned operation and the devices used. They will meet 6 monthly to review the data collected from the trial.

Participation in this study is entirely voluntary and you do not have to take part in it. If you do take part, you can withdraw at any time without having to give a reason. Whatever your decision, please be assured that it will not affect your medical treatment or your relationship with the staff who care for you.

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 additional costs associated with participating in this research project. There is no payment to participate in the study.

4 What do I have to do?

There are no special requirements for you to participate in the study.

5 Other relevant information about the research project

A total of 86 patients will take part in the study. They will be randomized into two groups, LigaSure group (43 patients) or Harmonic group (43 patients). The study will be conducted in the following hospitals: Norwest Private Hospital, Blacktown Hospital, Nepean Private Hospital, Nepean Hospital, Westmead Hospital. The project will involve researchers from these sites working in collaboration.

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 or your relationship with those treating you.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. The alternative option would be to have your surgical treatment with any type of device the surgeon prefers, which could be LigaSure, Harmonic or another device.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include contributing to clinical evidence of the efficacy of these two devices.

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

The possible risks may be longer operative time and slightly more blood loss. However, both LigaSure and Harmonic have been used by doctors to perform laparoscopic hysterectomies for several years. The safety of these two instruments has been well established in clinical practice. In addition, your doctor is able to use any other device to control blood loss if they are concerned, including changing from Harmonic to LigaSure, and vice versa. Your surgery will be performed routinely, as if you were not in a trial.

10 What will happen to my test samples?

The research project doesn't involve the collection of tissue. Your uterus will be sent for histopathology as a routine care, but we will record the size of the uterus and the histopathological findings.

11 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.

12 Can I have other treatments during this research project?

Whilst you are participating in this research project, you are able to take medications or treatments either for your current condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project.

13 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or 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 investigators up to the time you withdraw will form part of the research project results.

14 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable side effects
- The device being shown not to be effective
- The device being shown to work and not need further testing
- Decisions made in the commercial interests of the local regulatory/health authorities

15 What happens when the research project ends?

You will have ongoing follow-up as required by your gynaecological conditions.
We anticipate the entire study to take three years. At completion of this, we are able to provide a summary of the result to you, if you wish.

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. The original data collection forms will be kept in a locked filing cabinet in our office. Your data will be de-identified and then entered on to a computer database, which will be password protected. This information will be kept for 15 years after completion of the project. 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 study 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 New South Wales privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study 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 your surgery, you should contact your treating doctor as soon as possible and you will be assisted with arranging appropriate medical treatment. Your treating doctor will then review the complaint and follow the appropriate management pathway. If your complaint is in regards to a member of staff (doctors, nurses, etc), you can raise this with your treating doctor OR the Principal investigator. 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.

18 Who is organising and funding the research?

This research project is funded by the SWAPS unit and any scholarships obtained. This research project is being conducted by Dr Amy Feng and Dr Clare Wong, on behalf of the SWAPS unit.

You will not benefit financially from your involvement in this research 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).

There are no conflicts of interest from the study doctors and the SWAPS units.

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 Western Sydney Local Health District.

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 doctors Dr Clare Wong on 02-98818000 or Dr Amy Feng on 0402111802.

Clinical contact person

Name	Clare Wong
Position	Principal investigator
Telephone	0416067110
Email	Bonming_99@yahoo.com

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

Position	Office of the General Manager, Blacktown-Mt Druitt Hospitals
Telephone	98818000 (Blacktown Hospital switchboard) and ask to be connected to the Office of the General Manager
Email	wslhd-bmdhexec@health.nsw.gov.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	*Western Sydney Local Health District*
Telephone	02-8890 9007
Email	wslhd-researchoffice@health.nsw.gov.au

Health
NSW GOVERNMENT Western Sydney Local Health District

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Coordinating Principal Investigator/ Principal Investigator	Dr Amy Feng/ Dr Clare Wong
Associate Investigator(s)	Bassem Gerges, George Hardas, Imad Mahmoud, Harry Merkur, Yogesh Nikam, Luice Wang, Clare Wong, Amy Feng, Basia Slusarczyk
Location	Blacktown Hospital

Declaration by Participant

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 give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to ***Sydney West Advanced Pelvic Surgery Unit*** concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

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 study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please _____

Signature _____ Date _____

Name of Witness* to Participant's Signature (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.

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Form for Withdrawal of Participation - *Adult providing own consent*

Title	LigaSure Retractable L-Hook compared with Harmonic Ace +7 as a single instrument for total laparoscopic hysterectomy: Is bipolar energy superior to ultrasonic energy? - randomised controlled trial
Short Title	LigaSure L-Hook Vs Harmonic Ace +7 for total laparoscopic hysterectomy
Protocol Number	
Project Sponsor	Nil
Coordinating Principal Investigator/ Principal Investigator	Dr Amy Feng/ Dr Clare Wong
Associate Investigator(s)	Bassem Gerges, George Hardas, Imad Mahmoud, Harry Merkur, Yogesh Nikam, Luice Wang, Clare Wong, Amy Feng, Basia Slusarczyk
Location	Norwest Private Hospital, Blacktown Hospital, Nepean Private Hospital, Nepean Hospital, Westmead Hospital

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 ***Sydney West Advanced Pelvic Surgery Unit***.

Name of Participant (please print) _____

Signature _____ Date _____

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.