Online Forms
National Ethics Application Form

Within which Jurisdictions will your research application be submitted to: *(tick all that apply)*

- [x] New South Wales
- [ ] Queensland
- [ ] South Australia
- [ ] Victoria

HREC Application Reference Number:

1. TITLE AND SUMMARY OF PROJECT

1. Title

What is the formal title of this research proposal?
The comparison of surgical outcomes using LigaSure and Gyrus PK in total laparoscopic hysterectomy

What is the short title / acronym of this research proposal (if applicable)?
NA

2. Description of the project in plain language

Give a concise and simple description (not more than 400 words), in plain language, of the aims of this project, the proposal research design and the methods to be used to achieve those aims.

In laboratory based studies, Ligasure had the highest mean burst pressure and fastest blood sealing time when compared to other vessel sealing devices such as Enseal, Gyrus PK and Harmonic scalpel. Currently, clinical studies are needed to further evaluate the claimed advantages provided by LigaSure in laparoscopic gynaecological surgery. The aim of the study is to compare operative time and blood loss with the use of Ligasure versus Gyrus PK blood vessel sealing devices during laparoscopic hysterectomy.
This is a randomised controlled trial. All components used in this study are TGA approved and have been used for more than 10years. Women, who undergo a laparoscopic hysterectomy for benign indications will be randomised to the use of LigaSure or Gyrus PK blood vessel sealing devices. A total of 114 cases will be enrolled in the study. Operating time, intra-operative blood loss, major complications, post-operative analgesia usage, conversion rate, ergonomics and costs will be measured.

2. RESEARCHERS / INVESTIGATORS

1. Chief researcher(s)/investigator(s)
This question only applies to multi-centre research. If your research is not multi-centre, please leave this question blank. See Guidance Text (G) for the definition of a Chief Researcher

Chief researcher

	Title:	Forename/Initials:	Surname:
	Dr	Clare	Wong
Mailing Address:	26 Leone Ave		
Suburb/Town:	Baulkham Hills		
State:	NSW		
Postcode:	2153		
Country:	Australia		

Organisation:	Sydney West Advanced Pelvic Surgery Unit
Department*:	
Position:	Laparoscopic fellow
E-mail:	bonming_99@yahoo.com
Phone (BH):	0416067110
Phone (AH)*:	
Mobile*:	0416067110
Pager*:	
Fax:	

Is this person the contact person for this application?
○ Yes ○ No

Summary of qualifications and relevant expertise.
MBBS
MM(RHHG)
MRANZCOG

Please declare any general competing interests.
no competing interests

Name the site(s) for which this chief researcher / investigator is responsible.
Norwest Private Hospital
Blacktown Hospital

Describe the role of the chief researcher / investigator in this project.
being responsible to obtain ethics approval, and liaising with other investigators to conduct the study, ensuring the protocol is adhered completely and accurately, reviewing case report forms regularly for completeness and accurately

Is the chief researcher / investigator a student? ○ Yes ◉ No

2. Principal researcher(s) / investigator(s)

Principal researcher / investigator 1

Title:	Forename/Initials:	Surname:
Dr	Clare	Wong

Mailing Address:	26 Leone Ave
Suburb/Town:	Baulkham Hills
State:	NSW
Postcode:	2153
Country:	Australia
Organisation:	Sydney West Advanced Pelvic Surgery Unit
Department*:	
Position:	Laparoscopic fellow
E-mail:	bonming_99@yahoo.com
Phone (BH):	0416067110
Phone (AH)*:	0296599311
Mobile*:	0416067110
Pager*:	na
Fax:	0296599311

Is this person the contact person for this application?
◉ Yes ○ No

Summary of qualifications and relevant expertise
MBBS MM(RHHG) MRANZCOG

Please declare any general competing interests

no competing interests

Name the site(s) for which this principal researcher / investigator is responsible.
Norwest Private Hospital
Blacktown

Describe the role of the principal researcher / investigator in this project.
being responsible to obtain ethics approval, and liaising with other investigators to conduct the study, ensuring the protocol is adhered completely and accurately, reviewing case report forms regularly for completeness and accurately

Is the principal researcher a student? ○ Yes ◉ No

Principal researcher / investigator 2

Title:	Forename/Initials:	Surname:
Prof.	Harry	Merkur

Mailing Address:	6 Kempsey St
Suburb/Town:	Blacktown
State:	NSW
Postcode:	2148
Country:	Australia
Organisation:	Sydney West Advanced Pelvic Surgery Unit
Department*:	
Position:	The Director
E-mail:	hmerkur@bigpond.net.au
Phone (BH):	0296228000
Phone (AH)*:	
Mobile*:	0418290577
Pager*:	
Fax:	0296228686

Is this person the contact person for this application?
○ Yes ◉ No

Summary of qualifications and relevant expertise
MBBS
FRANZCOG
FRCOG

Please declare any general competing interests
No competing interests

Name the site(s) for which this principal researcher / investigator is responsible.
Norwest Private Hospital
Blacktown Hospital

Describe the role of the principal researcher / investigator in this project.
Providing supervision and advice, recruiting, consenting patients and performing the surgery

Is the principal researcher a student? ○ Yes ◉ No

3. Associate Researcher(s) / investigator(s)

How many known associate researchers are there? (You will be asked to give contact details for these associate researchers / investigators) 3

Do you intend to employ other associate researchers / investigators? ○ Yes ◉ No

Associate Researcher / Investigator 1

Title:	Forename/Initials:	Surname:
Dr	George	Hardas

Mailing Address:	6 Kemsey St
Suburb/Town:	Blacktown
State:	NSW
Postcode:	2148
Country:	Australia
Organisation:	Blacktown Hospital
Department*:	O&G
Position:	The Head of O&G department
E-mail:	george.hardas@bigpond.com
Phone (BH):	0296228000
Phone (AH)*:	
Mobile*:	
Pager*:	
Fax:	0296228686

Is this person the contact person for this application?
○ Yes ◉ No

Summary of qualifications and relevant expertise
MBBS
FRANZCOG

Please declare any general competing interests
no competing interests

Description of the role of the associate researcher / investigator in this project.
recruit, consent patients and perform surgeries

Name the site at which the associate researcher / investigator has responsibility.
Norwest Private Hospital
Blacktown Hospital

Is this associate researcher / investigator a student? ○ Yes ◉ No

Associate Researcher / Investigator 2

Title:	Forename/Initials:	Surname:
Dr	Luice	Wang

Mailing Address:	Nepean Private Hospital
	Consulting Suite 3
	1 Barber Ave
Suburb/Town:	Kinhwood
State:	NSW
Postcode:	2747
Country:	Australia
Organisation:	Nepean Hospital
Department*:	O&G
Position:	Consultant gynaecologist
E-mail:	eciul@yahoo.com
Phone (BH):	0247211555
Phone (AH)*:	
Mobile*:	
Pager*:	
Fax:	0247213479

Is this person the contact person for this application?
○ Yes ◉ No

Summary of qualifications and relevant expertise

MBBS
FRANZCOG

Please declare any general competing interests
no competing interests

Description of the role of the associate researcher / investigator in this project.
recruit, consent patients and perform surgeries

Name the site at which the associate researcher / investigator has responsibility.
Norwest Private Hospital

Is this associate researcher / investigator a student? ○ Yes ◉ No

Associate Researcher / Investigator 3

Title:	Forename/Initials:	Surname:
Dr	Vivian	Yang

Mailing Address:	unit 15 247 Ryedale Road
Suburb/Town:	Eastwood
State:	NSW
Postcode:	
Country:	Australia
Organisation:	Royal Prince Alfred Hospital
Department*:	O&G
Position:	consultant gynaecologist
E-mail:	vivianyang75@gmail.com
Phone (BH):	98747749
Phone (AH)*:	
Mobile*:	
Pager*:	
Fax:	98745543

Is this person the contact person for this application?
○ Yes ◉ No

Summary of qualifications and relevant expertise
MBBS

Please declare any general competing interests
no competing interests

Description of the role of the associate researcher / investigator in this project.
recruit, consent patients and perform surgeries

Name the site at which the associate researcher / investigator has responsibility.
Norwest Private Hospital

Is this associate researcher / investigator a student? ○ Yes ◉ No

5. Other personnel relevant to the research project

5a. How many known other people will play a specified role in the conduct of this research project?

2

5b. Describe the role, and expertise where relevant (e.g. counsellor), of these other personnel.

data entry and statistics analysis

5c. Is it intended that other people, not yet known, will play a specified role in the conduct of this research project?

○ Yes ◉ No

6. Certification of researchers / investigators

6a. Are there any relevant certification, accreditation or credentialing requirements relevant to the conduct of this research?

○ Yes ◉ No

7. Training of researchers

7a. Do the researchers / investigators or others involved in any aspect of this research project require any additional training in order to undertake this research?

○ Yes ◉ No

3. RESOURCES

Project Funding / Support

1. Indicate how the project will be funded?

Type of funding.

[Please note that all fields in any selected funding detail column (with the exception of the code) will need to be completed.]

Funding	Confirmed or Sought?	
External Competitive Grant	○ Confirmed ◉ Sought ○ Not Sought	*Amount of funding* 30,000
Internal Competitive Grant	○ Confirmed ○ Sought ◉ Not Sought	
Sponsor	○ Confirmed ○ Sought ◉ Not Sought	
By Researchers Department or Organisation	○ Confirmed ○ Sought ◉ Not Sought	

1a. External Competitive Grant

Name of Grant / Sponsor	AGES research fund
Code (optional)	
Detail in kind support	
Indicate the extent to which the scope of the grant and the scope of this HREC application are aligned:	This research project will continue whether the external grant is successful or not.

2. How will you manage a funding shortfall (if any)?

Sydney West Advanced Pelvic Surgery Unit will cover the shortfall.

3. Will the project be supported in other ways eg. in-kind support/equipment by an external party eg. sponsor?

○ Yes ◉ No

4. Is this a study where capitation payments are to be made, and will participants be made aware of these payments to clinicians or researchers / investigators?

No.

Duality of Interest

5. Describe any commercialisation or intellectual property implications of the funding/support arrangement.

NA

6. Does the funding/support provider(s) have a financial interest in the outcome of the research?

○ Yes ◉ No

7. Does any member of the research team have any affiliation with the provider(s) of funding/support, or a financial interest in the outcome of the research?

○ Yes ◉ No

8. Does any other individual or organisation have an interest in the outcome of this research?

○ Yes ◉ No

9. Are there any restrictions on the publication of results from this research?

○ Yes ◉ No

4. PRIOR REVIEWS

Ethical Review

Some HRECs may require researchers to provide information additional to that contained in a NEAF proposal. For this reason, it is prudent to check whether the HRECs to whom you propose to submit this proposal require additional information.

Duration and location

1. In how many Australian sites, or site types, will the research be conducted?

2

2. In how many overseas sites, or site types, will the research be conducted?

0

3. Provide the following information for each site or site type (Australian and overseas, if applicable) at which the research is to be conducted

1

Site / Site Type Name: Norwest Private Hospital

Site / Site Type Location: Bella Vista, NSW

2

Site / Site Type Name: Blacktown Hospital

Site / Site Type Location: Blacktown NSW

4. Provide the start and finish dates for the whole of the study including data analysis

Anticipated start date: 01/01/2015 *(dd/mm/yyyy)*

Anticipated finish date: 31/10/2017 *(dd/mm/yyyy)*

5. Are there any time-critical aspects of the research project of which an HREC should be aware?

○ Yes ◉ No

6. To how many Australian HRECs (representing site organisations or the researcher's / investigator's organisation) is it intended that this research proposal be submitted?

1

A list of NHMRC registered Human Research Ethics Committees (HRECs), along with their institutional affiliations and contact details is available on the NHMRC website at the following web address: http://www.nhmrc.gov.au/health_ethics/hrecs/overview.htm#d.

7. HRECs

HREC 1

Name of HREC:

Provide the start and finish dates for the research for which this HREC is providing ethical review:

Anticipated start date or date range: 01/11/2014 *(dd/mm/yyyy)*

Anticipated finish date or date range: 31/10/2017 *(dd/mm/yyyy)*

For how many sites at which the research is to be conducted will this HREC provide ethical review?

1

Site 1

Name of Site: Norwest Private Hospital

Principal Researcher 1

Principal Researcher Name:

Dr Clare Wong

Associate Researcher 1

Associate Researcher Name:

Dr Clare Wong

Site 2

Name of Site: Blacktown Hospital

Principal Researcher 1

Principal Researcher Name:
Dr Clare Wong

Associate Researcher 1

Associate Researcher Name:
Dr Clare Wong

8. Have you previously submitted an application, whether in NEAF of otherwise, for ethical review of this research project to any other HRECs?

○ Yes ◉ No

9. HRECs

Research conducted overseas

Peer review

11. Has the research proposal, including design, methodology and evaluation undergone, or will it undergo, a peer review process?

◉ Yes ○ No

Provide details of the review and the outcome. A copy of the letter / notification, where available, should be attached to this application.

5. PROJECT

1. Type of Research

Tick as many of the following 'types of research' as apply to this project. Your answers will assist HRECs in considering your proposal. A tick in some of these boxes will generate additional questions relevant to your proposal (mainly because the National Statement requires additional ethical matters to be considered), which will appear in Section 9 of NEAF.

The project involves:

☐ Research using qualitative methods

- [ ] Research using quantitative methods, population level data or databanks, e.g survey research, epidemiological research
- [x] Clinical research
- [ ] Research involving the collection and / or use of human biospecimens
- [ ] Genetic testing/research
- [ ] A cellular therapy
- [ ] Research on workplace practices or possibly impacting on workplace relationships
- [ ] Research conducted overseas involving participants
- [ ] Research involving ionising radiation
- [ ] Research involving gametes or use or creation of embryos
- [ ] None of the above

Does the research involve limited disclosure to participants?

○ Yes ◉ No

Does the research involve:

- [ ] Opt out approach
- [ ] Waiver
- [x] None of the above

Research plan

2. Describe the theoretical, empirical and/or conceptual basis, and background evidence, for the research proposal, eg. previous studies, anecdotal evidence, review of literature, prior observation, laboratory or animal studies.

The development of advanced vessel sealing devices has improved the efficiency and safety of laparoscopic surgical procedures1. The mean burst pressure, mean vessel seal time, thermal spread and smoke/vapour are the four main parameters of laparoscopic blood vessel sealing devices that have been assessed in laboratory based and animal studies. However, there is insufficient clinical evidence to support the use of one device over the other2. In laboratory based studies, LigaSure had the highest mean burst pressure and fastest blood sealing time when compared to other vessel sealing devices such as Enseal, Gyrus PK and Harmonic scalpel3. Currently, clinical studies are needed to further evaluate the claimed advantages provided by LigaSure in laparoscopic gynaecological surgery.

The LigaSure System is one of the advanced bipolar devices. It achieves vessel fusion by using the combination of pressure and high current low voltage (180V) energy. Instead of relying on a proximal thrombus to seal the vessel as seen in conventional bipolar instruments, a permanent fusion zone is created by melting the collagen and elastin in the vessel wall. The Feedback controlled system measures the tissue impedance changes 3,333 times per second and the energy output is adjusted accordingly. Once the desired tissue effect is achieved, the energy delivery is discontinued automatically and the surgeon is alerted by an audio signal. It is claimed that LigaSure not only provides excellent vessel sealing, but also avoids excessive energy, tissue charring and sticking.

Gyrus PK instruments use a pulsed energy delivery system, which can achieve an excellent coagulation with ultra-low voltage (110V). It also has a feedback control system to alert the surgeon with audio tone changes when the desired tissue effects have been accomplished. Therefore, it not only coagulates the tissue evenly, but also avoids

prolonged activation, tissue charring and sticking, in addition it minimizes lateral thermal spread. The serrated surface of the two-tier jaw and the curved fine rounded tip of the PK Lyons dissecting forceps provides good tissue grasping and atraumatic tissue dissection.
This study will provide clinical evidence of how the claimed advantages provided by LigaSure translate into the practicalities of laparoscopic gynaecological surgery. There is a potential time and cost saving if these claimed advantages are confirmed in the clinical setting.

3. State the aims of the research and the research question and/or hypotheses, where appropriate.

The aim of the study is to compare operative time and blood loss with the use of LigaSure versus Gyrus PK blood vessel sealing device during laparoscopic hysterectomy. It is to evaluate the claimed advantages provided by LigaSure in laparoscopic gynaecological surgery.

4. Has this project been undertaken previously?

○ Yes ◉ No

Benefits/Risks

In answering the following questions (Q 5 – 11) please ensure that you address all issues relevant to the type of participants that will be involved in your research project. Refer for guidance to relevant chapters of the National Statement.

5. Does the research involve a practice or intervention which is an alternative to a standard practice or intervention?

○ Yes ◉ No

7. What expected benefits (if any) will this research have for the wider community?

The research results will provide clinical evidence of how the claimed advantages provided by LigaSure are translated into laparoscopic gynaecological surgery. There is a potential time and cost saving in total laparoscopic hysterectomy if the claimed advantages provided by LigaSure are confirmed in the clinical setting.

8. What expected benefits (if any) will this research have for participants?

There is no direct benefit to the participants.

9. Are there any risks to participants as a result of participation in this research project?

○ Yes ◉ No

10. Explain how the likely benefit of the research justifies the risks of harm or discomfort to participants.

There is no additional risk to the participant. This study will provide clinical evidence of how the claimed advantages provided by LigaSure translated into laparoscopic gynaecological surgery. There is a potential time and cost saving if these claimed advantages provided by LigaSure are confirmed in the clinical setting.

11. Are there any other risks involved in this research? eg. to the research team, the organisation, others

○ Yes ◉ No

12. Is it anticipated that the research will lead to commercial benefit for the investigator(s) and or the research sponsor (s)?

○ Yes ◉ No

16. Is there a risk that the dissemination of results could cause harm of any kind to individual participants - whether their physical, psychological, spiritual, emotional, social or financial well-being, or to their employability or professional relationships - or to their communities?

○ Yes ◉ No

Monitoring

17. What mechanisms do the researchers / investigators intend to implement to monitor the conduct and progress of the research project?

Appoint a clinical monitor to review recruitment and case report forms regularly, provide progress report to the SWAPS research sub-committee.

18. Please detail your Data and Safety Monitoring Board (DSMB) and its nominee for this trial.

Dr Clare Wong will be the person responsible for the data collection and entry. The data set will be stored securely in a computer protected by an entry password.

6. PARTICIPANTS

1. Research participants

The National Statement identifies the need to pay additional attention to ethical issues associated with research involving certain specific populations.

This question aims to assist you and the HREC to identify and address ethical issues that are likely to arise in your research, if its design will include one or more of these populations. Further, the National Statement recognizes the cultural diversity of Australia's population and the importance of respect for that diversity in the recruitment and involvement of participants. Your answer to this question will guide you to additional questions (if any) relevant to the participants in your study.

Tick as many of the following 'types of research participants' who will be included because of the project design, or their inclusion is possible, given the diversity of Australia's population. If none apply, please indicate this below.

If you select column (a) or (b), column (c) will not apply.

The participants who may be involved in this research are: ***If you select column (a) or (b), column (c) will not apply.***	**a) Primary intent of research**	**b) Probable coincidental recruitment**	**c) Design specifically excludes**
People whose primary language is other than English (LOTE)	☐	☑	☐
Women who are pregnant and the human fetus	☐	☐	☑
Children and/or young people (ie. <18 years)	☐	☐	☑
People in existing dependent or unequal relationships	☐	☐	☑
People highly dependent on medical care	☐	☐	☑

People with a cognitive impairment, an intellectual disability or a mental illness	☐	☐	☑
Aboriginal and/or Torres Strait Islander peoples	☐	☑	☐
People who may be involved in illegal activity	☐	☑	☐
None apply	☐		

You have indicated that it is probable that
- People whose primary language is other than English (LOTE)
- Aboriginal and/or Torres Strait Islander peoples
- People who may be involved in illegal activity

may be coincidentally recruited into this project. The National Statement identifies specific ethical considerations for these groups(s).

Please explain how you will address these considerations in your proposed research.
There will be a medical interpreter provided for the consultation and consenting process.
There will be an Aboriginal liaison officer available if it is needed.

Participant description

2. How many participant groups are involved in this research project?

2

3. What is the expected total number of participants in this project at all sites?

114

4. Groups

Your response to question 1 at Section 6 - "Research Participants" indicates that the following participant groups are excluded from your research. If this is not correct please return to question 1 at Section 6 to amend your answer.

- Women who are pregnant and the human fetus
- Children and/or young people (ie. <18 years)
- People with an intellectual or mental impairment
- People highly dependent on medical care
- People in existing dependent or unequal relationships with any member of the research team, the researcher(s), and/or the person undertaking the recruitment/consent process (eg. student/teacher; employee/employer; warden/prisoner; officer, enlisted soldier; patient/doctor)

5. Have any particular potential participants or groups of participants been excluded from this research? In answering this question you need to consider if it would be unjust to exclude these potential participants.

Yes, Women age < 35, pregnancy or malignancy suspected, or uterus exceeding 14 weeks in size will be excluded from the study.

Participant experience

6. Provide a concise detailed description, in not more than 200 words, in terms which are easily understood by the lay reader of what the participation will involve.

Patients who are booked to undergo a laparoscopic hysterectomy and meet the inclusion criteria will be recruited. If

they agree to participate in the study they will be asked to sign a Participant Consent Form. As a participant, she will be randomized into two groups. One group of patients will undergo the laparoscopic hysterectomy using the blood vessel sealing device named Gyrus PK, which is the device we routinely use. The other group will undergo laparoscopic hysterectomy using the blood vessel sealing device named LigaSure, which is the device that has been used since 1990 with very recent update in technology and we are going to evaluate.
The researcher would also like to access to participants' pathology results and medical records.

Relationship of researchers / investigators to participants

7. Specify the nature of any existing relationship or one likely to rise during the research, between the potential participants and any member of the research team or an organisation involved in the research.

NA

9. Describe what steps, if any, will be taken to ensure that the relationship does not impair participants' free and voluntary consent and participation in the project.

Patients can withdraw at any time without having to give a reason. Whatever their decision, they will be assured that it will not affect their medical treatment or their relationship with the staff who care for them.

10. Describe what steps, if any, will be taken to ensure that decisions about participation in the research do not impair any existing or foreseeable future relationship between participants and researcher / investigator or organisations.

No coercion will compromise the commits or subsequent withdrawal by the patient. Their medical management will be the same.

11. Will the research impact upon, or change, an existing relationship between participants and researcher / investigator or organisations?

○ Yes ◉ No

Recruitment

13. What processes will be used to identify potential participants?

Patients who are booked for a total laparoscopic hysterectomy and meet the study inclusion/exclusion criteria will be approached by the investigator who will be the surgeon for the patient.

14. Is it proposed to 'screen' or assess the suitability of the potential participants for the study?

◉ Yes ○ No

How will this be done?
Patients who are booked for total laparoscopic hysterectomy will be identified as potential participants as long as they meet the study inclusion/exclusion criteria.

15. Describe how initial contact will be made with potential participants.

Patients who are booked for a total laparoscopic hysterectomy and meet the study inclusion/exclusion criteria will be approached by the investigator who will be the surgeon for the patient.

16. Do you intend to include both males and females in this study?

○ Yes ◉ No

Please explain why only one sex is involved in the study. In doing this you will need to demonstrate why this

approach is valid.
It is a research conduct on laparoscopic hysterectomy(remove a womb from a woman).

17. Is an advertisement, e-mail, website, letter or telephone call proposed as the form of initial contact with potential participants?

○ Yes ◉ No

18. If it became known that a person was recruited to, participated in, or was excluded from the research, would that knowledge expose the person to any disadvantage or risk?

○ Yes ◉ No

Consent process

19. Will consent for participation in this research be sought from all participants?

◉ Yes ○ No

Will there be participants who have capacity to give consent for themselves?
◉ Yes ○ No

What mechanisms/assessments/tools are to be used, if any, to determine each of these participant's capacity to decide whether or not to participate?
These participants are the patients who are judged as being able to give consent for their surgical treatment by the principal surgeon.

Are any of the participants children or young people?
○ Yes ◉ No

Will there be participants who do not have capacity to give consent for themselves?
○ Yes ◉ No

The following questions relate to participants who are able to provide consent and also to participants for whom consent may be provided by a person with legal authority to do so. When answering these questions you need to describe any differences in the processes followed, or the documentation used, for different groups of participants in your proposal, e.g. processes and documentation for users of facilities/services will differ from those for providers of those facilities/services. Where your proposal involves participants with an intellectual or mental impairment, or people in dependent relationships, additional questions about their consent appear at section 7 questions 19-20 and questions 15-18 respectively.

Describe the consent process, ie how participants or those deciding for them will be informed about, and choose whether or not to participate in, the project. There will be multiple consultations. Written information will also be provided to the participants. There will be NO patients recruited who cannot undergo the consent process themselves.
If a participant or person on behalf of a participant chooses not to participate, are there specific consequences of which they should be made aware, prior to making this decision? No
Might individual participants be identifiable by other members of their group, and if so could this identification could expose them to risks? No
If a participant or person on behalf of a participant chooses to withdraw from the research, are there specific consequences of which they should be made aware, prior to giving consent? No
Specify the nature and value of any proposed incentive/payment (eg. movie tickets, food vouchers) or reimbursement (eg travel expenses) to participants. NA
Explain why this offer will not impair the voluntary nature of the consent, whether by participants' or persons deciding for their behalf. NA

Do you propose to obtain consent from individual participants for your use of their stored data/samples for this research project?
◉ Yes ○ No

7. Participants Specific

8. CONFIDENTIALITY/PRIVACY

Answers to the questions in section 8.1 will establish whether an HREC will need to apply guidelines under federal or State/territory privacy legislation in reviewing your application. Answers to questions in the remaining parts of section 8 will show how confidentiality of participants is to be protected in your research.

1. Do privacy guidelines need to be applied in the ethical review of this proposal?

Indicate whether the source of the information about participants which will be used in this research project will involve:

- [x] collection directly from the participant
- [ ] collection from another person about the participant
- [ ] use or disclosure of information by an agency, authority or organisation other than your organisation
- [ ] use of information which you or your organisation collected previously for a purpose other than this research project

Information which will be collected for this research project directly from the participant

Describe the information that will be collected directly from participants. Be specific where appropriate.
Age, BMI, Parity: NVD/ CS, Indication of surgery, Uterine length and width,
Previous surgical history, Pathology, Uterine weight , operating time (from initial skin incision till detachment of the uterus with secured haemostasis), total operating time (from initial skin incision till final skin closure, intra-operative blood loss, major complications, post op analgesia usage, conversion rate, ergonomics,costs

The information collected by the research team about participants will be in the following form(s). Tick more than one box if applicable.

- [ ] individually identifiable
- [ ] re-identifiable
- [x] non-identifiable

Will consent be sought from participants (or for participants from persons with legal authority) for the collection and use of information about them?

○ Yes ○ No

1c. Will the information to be used in medical research?

◉ Yes ○ No

1d. Does this application include an attachment relevant to state/territory privacy legislation?

○ Yes ◉ No

1e. Is the information health information?

◉ Yes ○ No

Using information from participants

2. Describe how information collected about participants will be used in this project.

All the information collected from the participant for the study will be treated confidentially, and only the researchers named above will have access to it. The study results may be presented at a conference or in a scientific publication, but individual participants will not be identified in such a presentation

3. Will any of the information be used by the research team be in identified or re-identifiable (coded) form?

○ Yes ◉ No

4. List ALL research personnel and others who, for the purposes of this research, will have authority to use or have access to the information and describe the nature of the use or access. Examples of others are: student supervisors, research monitors, pharmaceutical company monitors.

principle researcher and co-researchers

Storage of information about participants during and after completion of the project

5. In what formats will the information be stored during and after the research project? (eg. paper copy, computer file on floppy disk or CD, audio tape, videotape, film)

paper copy and computer file

6. Specify the measures to be taken to ensure the security of information from misuse, loss, or unauthorised access while stored during and after the research project? (eg. will identifiers be removed and at what stage? Will the information be physically stored in a locked cabinet?)

The identifier will be removed after the statistics analysis. All the information will be physically stored in the locked cabinet in SWAPS office.

9. The information which will be stored at the completion of this project is of the following type(s). Tick more than one box if applicable.

- ☐ individually identifiable
- ☐ re-identifiable
- ☑ non-identifiable

10. For how long will the information be stored after the completion of the project and why has this period been chosen?

The information will be stored indefinitely since it is stored in a non-identifiable form.

11. What arrangements are in place with regard to the storage of the information collected for, used in, or generated by this project in the event that the principal researcher / investigator ceases to be engaged at the current organisation?

All the information collected for , used in or generated by this project will stay with Sydney West Advanced Pelvic Surgery Unit.

Ownership of the information collected during the research project and resulting from the research project

13. Who is understood to own the information resulting from the research, eg. the final report or published form of the

results?

Dr Clare Wong, Prof. Merkur and associated investigators will own the final report of the results.

14. Does the owner of the information or any other party have any right to impose limitations or conditions on the publication of the results of this project?

○ Yes ◉ No

Disposal of the information

15. Will the information collected for, used in, or generated by this project be disposed of at some stage?

○ Yes ◉ No

Reporting individual results to participants and others

16. Is it intended that results of the research that relate to a specific participant be reported to that participant?

○ Yes ◉ No

Explain/justify why results will not be reported to participants:
The research result has no personal significance to the individual participant.

17. Is the research likely to produce information of personal significance to individual participants?

○ Yes ◉ No

18. Will individual participant's results be recorded with their personal records?

◉ Yes ○ No

19. Is it intended that results that relate to a specific participant be reported to anyone other than that participant?

○ Yes ◉ No

20. Is the research likely to reveal a significant risk to the health or well being of persons other than the participant, eg family members, colleagues

○ Yes ◉ No

21. Is there a risk that the dissemination of results could cause harm of any kind to individual participants - whether their physical, psychological, spiritual, emotional, social or financial well-being, or to their employability or professional relationships - or to their communities?

○ Yes ◉ No

22. How is it intended to disseminate the results of the research? eg report, publication, thesis

The study results may be presented at a conference or in a scientific publication

23. Will the confidentiality of participants and their data be protected in the dissemination of research results?

(•) Yes ( ) No

Explain how confidentiality of participants and their data will be protected in the dissemination of research results:
Individual participants will not be identified in such a presentation or publication.

9. PROJECT SPECIFIC

Your responses to question 5.1 "Type of Research" and question 6.1 "Research participants" indicate that the HREC will require additional information which is specific to your research project. The following table indicates the question sets relating to the project that you will need to complete. If this is not correct please return to question 5.1 and 6.1 at to amend your answer.

- 9.1. Type of research/trial
- 9.2. Clinical research

9.1 Type of research/trial

1. The study involves:

- [ ] The administration of a drug / medicine (includes a complementary / alternative medicine)
- [x] The use of a medical device
- [ ] The administration of human somatic cell gene therapy
- [ ] The use of a xenotransplant
- [ ] The use of stem cells (adult or embryonic) as therapy
- [ ] Other

2. The project will be conducted as follows:

Under the Clinical Trial Notification Scheme (CTN) ( ) Yes (•) No

Under the Clinical Trial Exemption Scheme (CTX) ( ) Yes (•) No

You have indicated that you are conducting a clinical trial under neither the CTN or CTX scheme. Please ensure that this is correct by referring back to your answer at Page 16, Section 5, Question 1 'Type of Research' If you are conducting a trial in clinical setting, which will not take place under CTN or CTX, please ensure that enough detail has been provided about the research to allow a HREC to adequately review it. This may require you to review your answers in Page 16, Section 5, Quest Type of Research and/or Page 20, Section 6, Question 1 Research participants

3. Provide the following details for the clinical trial protocol:

Protocol name:
Protocol version number:
Protocol version date: *(dd/mm/yyyy)*

If you intend to/have registered this trial in a publicly accessible register, please provide the details of it here

4. Provide the following details for the investigator's brochure/product information (as relevant):

Title of Investigator's Brochure:
Investigator's brochure version number:
Investigator's brochure version date: *(dd/mm/yyyy)*

Use of a medical device under the CTN/CTX scheme

5. Describe the trial phase for the medical device.

These two laparoscopic blood vessel sealing devices are TGA listed and have been widely used in laparoscopic surgery for more than 10 years.

6. How many devices, including comparators, are being tested in the trial?

2

7. Provide the following information for each device:

Device 1

Approved name:	Gyrus PKS Lyons dissecting forceps
Trade name:	Gyrus PKS Lyons dissecting forceps
Known adverse effects:	thermal injury
Known contra-indications/warnings:	No
Length of time participants will be monitored for adverse reactions:	2 weeks

Has the sponsor or manufacturer agreed to supply the device free of charge for the duration of the trial?
○ Yes ◉ No

Describe what arrangements have been made for the supply of the device:
This is a laparoscopic instrument that is purchased and stocked routinely by the hospitals where the research will be conducted.

Is the device implantable?
○ Yes ◉ No

Will the trial device/treatment be made available to participants after the completion of the trial?
◉ Yes ○ No

Explain who will have access to the trial device, under what conditions, for how long and who will pay for the device/treatment:
This laparoscopic blood vessel sealing device is TGA listed and has been widely used in laparoscopic surgery for more than 10 years. It is available to laparoscopic surgeons in many hospitals.

Device 2

Approved name:	LigaSure VTM laparoscopic sealer/divider
Trade name:	LigaSure VTM laparoscopic sealer/divider
Known adverse effects:	thermal injury
Known contra-indications/warnings:	No
Length of time participants will be monitored for adverse reactions:	2 weeks

Has the sponsor or manufacturer agreed to supply the device free of charge for the duration of the trial?
○ Yes ◉ No

Describe what arrangements have been made for the supply of the device:
This is a laparoscopic instrument that is purchased and stocked routinely by the hospitals where the research will be conducted

Is the device implantable?
○ Yes ◉ No

Will the trial device/treatment be made available to participants after the completion of the trial?
◉ Yes ○ No

Explain who will have access to the trial device, under what conditions, for how long and who will pay for the device/treatment:
This laparoscopic blood vessel sealing device is TGA listed and has been widely used in laparoscopic surgery for more than 10 years. It is available to laparoscopic surgeons in many hospitals

9.2 Clinical research

1. The study examines:

- ☐ The administration of a drug / medicine (includes a complementary / alternative medicine)
- ☑ The use of a medical device
- ☐ Other

2. Provide the following details for the study protocol:

Protocol title:
Protocol version number:
Protocol version date: *(dd/mm/yyyy)*

3. Provide a statement addressing the following as may be applicable to the project.

a) Method of randomisation
b) Whether the hypothesis offers a realistic possibility that the intervention is at least as effective as standard treatment
c) The justification for the use of placebo or non-treatment control group, including alternative effective treatments and any risk of harm in the absence of treatment.
d) How variations in response will be treated
e) Endpoints
f) Details of contingencies and management of these
g) Explain the arrangements in place to ensure there is adequate compensation for participants.

57 patients per study group will be enrolled. Enrolment is defined as completion of informed consent and randomisation. An online random number generator will be used for randomization. The randomization outcome will be written on a paper and put in numbered opaque envelopes, which will be opened by the surgeons in theatre just before the operation. The randomisation scheme, in a blocking size 8 (4 of each treatment), will be used to generate the randomisation list. The randomisation scheme will insure that during the enrolment period the ratio of the number of cases in the two groups remain approximately constant.
The LigaSure VTM laparoscopic 37cm sealer /divider and Gyrus PKS™ LYONS™ 33cm dissecting forceps are commercially available, TGA (Therapeutic Goods Administration) listed devices. All components of the system have been approved for sale and use throughout Australia. These two devices have been used in laparoscopic procedures for more than ten years. Therefore, there will be no additional risk to participants.
The endpoints of this study are operative time and blood loss.

4. How many drugs will be used in this research project?

0

10. Declarations And Signatures

Applicant / Principal Researchers (including students where permitted)

Project Title (in full):	The comparison of surgical outcomes using LigaSure and Gyrus PK in total laparoscopic hysterectomy
HREC to which this application is made:	
HREC Reference number:	

I/we certify that:

- All information is truthful and as complete as possible.
- I/we have had access to and read the National Statement on Ethical Conduct in Research InvolvingHumans.
- The research will be conducted in accordance with the National Statement.
- The research will be conducted in accordance with the ethical and research arrangements of the organisations involved.
- The research will be conducted in accordance with the ethical and research arrangements of the organisations involved.
- I/we have consulted any relevant legislation and regulations, and the research will be conducted in accordance with these.
- I/we will immediately report to the HREC anything which might warrant review of the ethical approval of the proposal (NS 2.37), including:
- serious or unexpected adverse effects on participants;
- proposed changes in the protocol; and
- unforseen events that might affect continued ethical acceptability of the project.
- I/we will inform the HREC, giving reasons, if the research project is discontinued before the expected date of completion (NS 2.38);
- I/we will not continue the research if ethical approval is withdrawn and will comply with any special conditions required by the HREC (NS. 2.45);
- I/we will adhere to the conditions of approval stipulated by the HREC and will cooperate with HREC monitoring requirements. At a minimum annual progress reports and a final report will be provided to the HREC.

Applicant / Chief Researcher(s) / Principal Researcher(s)

Dr Clare Wong Sydney West Advanced Pelvic Surgery Unit	..... Signature	...../ ...../ ..... Date
Dr Clare Wong Sydney West Advanced Pelvic Surgery Unit	..... Signature	...../ ...../ ..... Date
Prof. Harry Merkur Sydney West Advanced Pelvic Surgery Unit	..... Signature	...../ ...../ ..... Date

Associate Researchers

Dr George Hardas Blacktown Hospital	..... Signature	...../ ...../ ..... Date
Dr Luice Wang Nepean Hospital	..... Signature	...../ ...../ ..... Date
Dr Vivian Yang Royal Prince Alfred Hospital	..... Signature	...../ ...../ ..... Date

Supervisor(s) of student(s)

Project Title (in full):	The comparison of surgical outcomes using LigaSure and Gyrus PK in total laparoscopic hysterectomy
HREC to which this application is made:	
HREC Reference number:	

I/we certify that:

- I/we will provide appropriate supervision to the student to ensure that the project is undertaken in accordance with the undertakings above;
- I/we will ensure that training is provided necessary to enable the project to be undertaken skilfully and ethically.

Heads of departments/schools/research organisation

Project Title (in full):	The comparison of surgical outcomes using LigaSure and Gyrus PK in total laparoscopic hysterectomy
HREC to which this application is made:	
HREC Reference number:	

I/we certify that:

- I/we are familiar with this project and endorse its undertaking;
- the resources required to undertake this project are available;
- the researchers have the skill and expertise to undertake this project appropriately or will undergo appropriate training as specified in this application.

..... Title

..... First Name

..... Surname

..... Position

..... Organisation Name

..... Signature

...../ ...../ ..... Date

11. Attachments

List of Attachments

Core Attachments	Attachments which may be required/appropriate
Recruitment/invitation	Copy of advertisement, letter of invitation etc
Participant Information	Copy or script for participant Copy or script for parent, legal guardian or person responsible as appropriate
Consent Form	Copy for participant For parent, legal guardian or person responsible as appropriate For, optional components of the project eg. genetic sub study
Peer review	Copy of peer review report or grant submission outcome
HREC approvals	Copy of outcome of other HREC reviews

Attachments specific to project or participant group	Attachments which may be required/appropriate
People whose primary language is other than English (LOTE)	English translation of participant information/consent forms
Aboriginal and/or Torres Strait Islander peoples	Evidence of support / permission of elders and/or other appropriate bodies

Participant information elements

Core Elements
Provision of information to participants about the following topics should be considered for all research projects.

Core Elements	Issues to consider in participant information
About the project	Full title and / or short title of the project Plain language description of the project Purpose / aim of the project and research methods as appropriate Demands, risks, inconveniences, discomforts of participation in the project Outcomes and benefits of the project Project start, finish, duration
About the investigators / organisation	Researchers conducting the project (including whether student researchers are involved) Organisations which are involved / responsible Organistions which have given approvals Relationship between researchers and particpants and organisations
Participant description	How and why participants are chosen How participants are recruited How many participants are to be recruited
Participant experience	What will happen to the particant, what will they have to do, what will they experience? Benefits to individual, community, and contribution to knowledge Risks to individual, community

	Consequences of participation
Participant options	Alternatives to participation Whether participation may be for part of project or only for whole of project Whether any of the following will be provided: counselling, post research follow-up, or post research access to services, equipment or goods
Participants rights and responsibilities	That participation is voluntary That participants can withdraw, how to withdraw and what consequences may follow Expectations on participants, consequences of non-compliance with the protocol How to seek more information How to raise a concern or make a complaint
Handling of information	How information will be accessed, collected, used, stored, and to whom data will be disclosed Can participants withdraw their information, how, when Confidentiality of information Ownership of information Subsequent use of information Storage and disposal of information
Unlawful conduct	Whether researcher has any obligations to report unlawful conduct of participant
Financial issues	How the project is funded Declaration of any duality of interests Compensation entitlements Costs to participants Payments, reimbursements to participants Commercial application of results
Results	What will particpants be told, when and by whom Will individual results be provided What are the consequences of being told or not being told the results of research How will results be reported / published Ownership of intellectual property and commercial benefits
Cessation	Circumstances under which the participation of an individual might cease Circumstances under which the project might be terminated

Research Specific Elements

Provision of information to participants about the following topics should be considered as may be relevant to the research project.

Specific to project or participant group	**Additional issues to consider in participant information**
Aboriginal and/or Torres Strait Islander peoples	Describe consultation process to date and involvement of leaderswhether ATSI status will be recorded