**Appendix 2:**

PICF - Patient:

**Participant Information Sheet/Consent Form**

**Interventional Study** -*Adult providing own consent*

*[Insert site name]*

|  |  |
| --- | --- |
| **Title** | Matched comparison of gastro-enterostomy construction: Quantify differences in technical proficiency and precision of robotic versus laparoscopic platform |
| **Short Title** | Gastro-enterostomy matched comparison |
|  |  |
| **Project Sponsor** | Nil |
| **Coordinating Principal Investigator/ Principal Investigator** | Yit Leang |
| **Associate Investigator(s)** | Paul Burton, Wendy Brown, Chrys Hensman |
| **Location** | Victoria   1. Alfred Health, Melbourne 2. The Avenue Private Hospital, Melbourne 3. Cabrini Hospital, Melbourne 4. The Valley Private Hospital (Mulgrave Private), Melbourne 5. Department of Surgery, Central Clinical School, Monash University 6. Epworth Richmond Hospital, Melbourne   New South Wales   1. St. George Private Hospital, Sydney 2. St. Vincent Private Hospital, Sydney   Queensland   1. John Flynn Private Hospital, Tugun 2. Pindara Private Hospital, Benowa   South Australia   1. Flinders Private Hospital, Bedford Park   Western Australia   1. St. John of God – Wexford Medical Centre, Murdoch |

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project. This is because you will be having a minimally invasive operation (laparoscopic or robotic) by one of the surgeons involved in the trial. The research project will compare the technical advantages and disadvantages of the newer robotic platform against the well-established, widely available and safe conventional laparoscopic platform for minimally invasive surgery. This will not alter your treatment or operation at all but will involve the surgeon and his/her team completing a survey AFTER your operation is completed.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments 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?**

Currently, minimally invasive operation is performed using conventional laparoscopic platform comprises of a 2-dimensional camera and long straight surgical instruments with 4-axis of motions. This has been proven to be a safe and effective way of performing minimally invasive surgery and widely adopted worldwide by many surgeons.

Newer technology such as the robotic platform with 3-dimensional camera and 7-axis of motion surgical instruments has since been introduced. The enhanced visual optics and flexibility of the robotic instruments have been designed to improve the accuracy and technical execution of complex minimally invasive procedures such as bariatric surgeries.

This newer robotic technology cost more and published surgical results on the use of robotic platform for bariatric procedures have not been conclusive to justify the cost of this technology. This is because conventional laparoscopic surgery is very safe and hence proving a superior clinical outcome will require a lot of study and research data.

Other ways to compare the 2 platforms is to evaluate and compare the technical advantages and disadvantages using established surgical proficiency and difficulty tools. The aim of this study is to scientifically measure if robotic platform makes a complex laparoscopic procedure easier to perform and how it does so to help surgeons understand and choose the best tools to perform your operation to achieve the best possible outcome.

The results of this research will be used by the study doctor Dr. Yit Leang to obtain a Doctor of Philosophy degree.

This research has been initiated by the study doctor, Dr Yit Leang.

This research has no external funding.

This research is being conducted by the investigators listed above, at the hospitals listed above.

This research is being conducted without commercial sponsorship.

**3 What does participation in this research involve?**

⮞ Consent form will be signed prior to any study assessments being performed.

⮞ Initial steps

• Screening for eligibility: If you are undergoing laparoscopic or robotic bariatric gastric bypass procedure being performed by a study surgeon, you will be eligible for the trial.

⮞ Procedures

• Procedures: Laparoscopic or robotic bariatric gastric bypass

• Involvement in the trial will not alter your treatment in any way. The trial involves your surgeon recording your procedure. Your surgeon and surgical team completing a survey of how difficult or easy the operation was to perform AFTER your procedure is completed. The video of your procedure will be reviewed by 2 surgeons and difficulty of the procedure evaluated using developed tools.

• Follow-up: You will be followed up by your surgeon and team in the normal manner. Involvement in the trial will not alter your routine care.

• Duration of your involvement will only be during performance of the operation. It is expected that it will take 6-18 months to recruit the number of participants required to complete the trial.

⮞ Reimbursement and costs – There will be no additional costs. There will be no reimbursement.

⮞ How the research will be monitored: The Alfred Human Research Ethics committee will monitor the research project.

⮞ The commitment required by the participant: Allowing the intra-abdominal component of the procedure to be video recorded (you will be not identified on the video as only the internals are being recorded), allowing the surgeon and team to complete the survey at completion of the operation, allowing your demographics details (excluding identifiable information) to be recorded for the trial.

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, nor will you be paid.

You will not need to be reimbursed for any costs as there will be no additional expenses associated with the research project beyond your normal care.

**4 What do I have to do?**

The study will not change your procedure or normal care. You do not need to do anything extra to be involved in the study. You will provide consent to:

1. The surgeon and surgical team completing a survey about the difficulty of your surgery after completing your procedure.
2. Capturing and storing an internal video of your procedure being performed where you are not being identified in any way.
3. Obtaining and storing your general demographic data and some basic surgical outcome measurements.

**5 Other relevant information about the research project**

This is a national study and will involve other surgeons at other hospitals enrolling their patients into this study. All surgeons will be 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, your relationship with those treating you or your relationship with your treating hospital.

**7 What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at this hospital. If you do not take part in this study, your operation and care will proceed as normal.

**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 progressing our understanding on the use of the new robotic surgical platform and achieve better surgical outcomes in the future.

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

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

We are aware of the importance of patient privacy and will take every precaution to protect your important personal information. This includes the internal surgical recording of your procedure along with your basic de-identified demographic and basic surgical outcome data. This data will be recorded on a password protected database.

**10 What will happen to my internal video?**

This will be stored securely and analysed for the study.

**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.

**12 Can I have other treatments during this research project?**

Whilst you are participating in this research project, you can have all appropriate treatments that relate to your routine surgical care.

**13 What if I withdraw from this research project?**

If you decide to withdraw from the project, please notify Dr. Yit Leang (co-Principal Investigator) at 03-9903 0190.

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.

**14 Could this research project be stopped unexpectedly?**

It is not expected that this study will stop between you consenting to the trial and then undergoing surgery.

**15 What happens when the research project ends?**

The results will be analysed, published and presented at surgical meetings to report the results of this research. It is hoped that this study will better inform surgeons on the technical advantages of robotic surgical platform in bariatric surgery and the information help develop future studies to validate this result.

Participants can request the results and publications be made available to them within 12 months of the study being completed.

**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 internal video recorded during your surgery will not be able to identify you and will only be identifiable by your unique study number. Your demographic data, medical history and information on surgery will be recorded in a password protected database. 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.

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. No personal information will be attached to the study outcomes data or internal video recording. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and Victorian 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 and for the future research described in Section 16 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 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. If you do not have private health insurance, you may incur additional costs if you choose to receive medical care at a private hospital where the medical care is unrelated to the research project.’

**Compensation**

The avenue that may be available to you for seeking compensation if you suffer an injury as a result of your participation in this research project:

• You may be able to seek compensation through the courts.

**18 Who is organising and funding the research?**

This research project is being conducted by Yit Leang

This research project is not being sponsored or externally funded.

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).

**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 The Alfred 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.

**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 doctor on 03 9903 0190.

**Clinical contact person**

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| --- | --- |
| Name | *Yit Leang* |
| Position | *Co-Principal Investigator* |
| Telephone | *03 9903 0190* |
| Email | *Yit.leang@monash.edu* |

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 (**Please quote the following Project ID number 91593; Local reference 89/23)

|  |  |
| --- | --- |
| Name |  |
| Position |  |
| Telephone |  |
| Email |  |

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 name | *Alfred Health Ethics and Research Governance* |
| HREC Executive Officer | *Julia Yuncken* |
| Telephone | *03 9076 0590* |
| Email | *research@alfred.org.au* |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Consent Form -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | Matched comparison of gastro-enterostomy construction: Quantify differences in technical proficiency and precision of robotic versus laparoscopic platform |
| **Short Title** | Gastro-enterostomy matched comparison |
| **Project Sponsor** | Monash University |
| **Coordinating Principal Investigator/**  **Principal Investigator** | Yit Leang |
| **Associate Investigator(s)** | Paul Burton, Wendy Brown, Chrys Hensman |

**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 give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Monash Universityconcerning 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.

**Declaration by Participant – for participants who have read the information**

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| Name of Participant (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| 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. 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.

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|  | | | | | | |
|  | 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.

* Consent was obtained using telehealth with *[Name of Participant]* whose photographic identification was sighted by the Investigator who observed the Participant’s signature being written
* Consent was obtained via telephone with *[Name of Participant]* on [DD/MMM/YYYY].
* Participant’s signed consent form received by the Investigator on [DD/MMM/YYYY].
* Consent was obtained using telehealth with *[Name of Investigator]* whose photographic identification was sighted by the Participant who observed the Investigator’s signature being written
* Consent was obtained via telephone with *[Name of Investigator]* on [DD/MMM/YYYY].
* Discussed with *[Participant]* via telephone on *[insert date]* and received signed consent form on *[insert date]*. Signed by *[Investigator].*

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

|  |  |
| --- | --- |
| **Title** | Matched comparison of gastro-enterostomy construction: Quantify differences in technical proficiency and precision of robotic versus laparoscopic platform |
| **Short Title** | Gastro-enterostomy matched comparison |
| **Project Sponsor** | Nil |
| **Coordinating Principal Investigator/**  **Principal Investigator** | Yit Leang |
| **Associate Investigator(s)** | Paul Burton, Wendy Brown, Chrys Hensman |

**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 *[Institution]*.

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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**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.

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|  | | | | | | |
|  | 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.