Austin HEALTH

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Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Austin Health

Title	**SOOThe**: **S**tudy of **O**besity-reduction and **O**piate-free **T**IVA
Short Title	Opiate-free TIVA and Bariatric Surgery
Protocol Number	1
Coordinating Principal Investigator/	Dr Douglas Hacking
Associate Investigator(s)	Justin Nazarath, Ranj Guha, Daniel Banyasz & Kit James
Location	Austin 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 going to general surgery for weight loss. The research project is examining what happens if we keep you asleep with a gas that you breath (also known as Volatile Anaesthesia) or maintain your sleep with a constant infusion of intravenous drugs which is called Total Intravenous Anaesthesia or TIVA for short.

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?

This project is looking at the effect of different type of anaesthesia on how patients recovery from general surgery for being over-weight, otherwise known as bariatric surgery.

The background to this study is as follows. Being overweight is associated with a number of healthcare problems such as heart disease, diabetes and early joint replacement which are best avoided if at all possible. We know that the combination of medical treatment (that is the prescription of drugs) and surgery leads to the best outcomes in terms of long term weight loss. So the Anaesthetic Department is very much in favour of surgery to help overweight patients and will do everything we can to make sure it is a success.

One of the problems we face in giving an anaesthetic in the course of bariatric surgery is that the risks of the procedure are slightly higher if the patient is overweight. This study is trying to understand how we can minimise those risks.

At present we use two types of anaesthesia which are commonly used in weight loss surgery.

The first is anaesthesia with a gas (otherwise known as Volatile Anaesthesia) which is the traditional tried and tested means of putting patients to sleep. This involves giving intravenous drugs through the drip and then when the patient is asleep giving them a gas to breath which keeps them asleep. Lots of other drugs are given intravenously through the operation to help the surgical process. Examples include drugs to prevent pain like Morphine or Oxycodone and drugs to stop patients feeling sick. So the key difference here is that patients stay asleep through breathing the gas whilst getting other drugs through the drip. This works very well and is a very safe way to have your weight loss surgery done.

The second is anaesthesia only with intravenous drug which is called Total Intravenous Anaesthesia or TIVA. Here the patient is put to sleep in the same way as they would be if they would be if they were getting a Gas or Volatile Anaesthetic but their sleep in maintained with an infusion of the same drug that put them to sleep in this case Propofol which looks milky white. This is a slightly newer anaesthetic technique which is being used a little more now. As with volatile anaesthetic it is very safe and a tried and tested way of keeping someone asleep whilst having weight loses surgery.

No anaesthetic technique is risk free though the chance of a complication occurring is very, very low. One of the worries we have with weight loss surgery is whether the pain killing drugs, such as Morphine and Oxycodone- known collectively as Opioids, will either make patients sick or make them too drowsy. One of the problems about TIVA is the risk of patients not being fully asleep. However, this alarming complication this is corrected almost entirely by using a special monitor (called Sedline or BIS) to measure the brain waves and lets the Anaesthetist knows you are fully anaesthetised.

There are reports of using TIVA without Opiate drugs. We have been using this method for about two years within our department. This Opiate-free TIVA seems to work very well and may even be better than the traditional Volatile Anaesthesia using Opiates. However, we need to be sure that this is true so we have designed a study to find out.

The research is being conducted by Drs Douglas Hacking, Justin Nazareth, Ranj Guha Daniel Banyasz and Kit James who are all in the Department of Anaesthesia at Austin Health and are the Anaesthetists who do the anaesthesia for the weight loss surgery.

3 What does participation in this research involve?

You will be participating in a study because you are having weight loss surgery. You will be allocated into either the Volatile and Opiate Group or the Opiate free TIVA Group- we do this at random or put another way by chance.

Your study doctor will know which group you are in, but you will not know which group you are in. The anaesthetic will seem the same to you whether you get Volatile and Opiates or Opiate free TIVA. You may not feel any different in this anaesthetic as to others you have had in the past. The differences, if they are present, are likely to be very subtle so the study will not have much of a effect on your stay in hospital. All patients will have brain monitoring by Sedline or BIS which is a sticky tape which sits on your forehead.

Note that you will only be approached for consent if you are eligible to participate. Also, all data will only be collected after you sign the consent form.

We will collect information from your medical history and from data that is routinely measured during your anaesthetic care. You will undergo general surgery as per standard practice with the following additional procedures:

1. You will be asked in recovery how you feel with respect to pain, feeling sick and how quickly you have recovered from the surgery and Anaesthetic. We would ask these questions anyway regardless of the study. What is different is that the answers will be linked to the type of anaesthetic you had.

2. These questions will be repeated on Day 1 and Day 2 on the ward. They will take no more than 5 minutes to complete and if you are feeling tired or wish to be left alone we can always come back later in the day and ask those questions at a more convent time.

3. We will use the medical charts to note how many pain killers or Opiate you needed and how many anti-sickness drugs you required.

There will be no further involvement of your time and no further commitment required.

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. So the Nurses and Doctors in PACU and on the post operative ward will not know which anaesthetic you had.

There are no additional costs associated with participating in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you free of charge.

4 What do I have to do?

Participants will undergo general surgery as per standard practice, with a few extra procedures as described in Section 3. There are no lifestyle or dietary restrictions with this study. There are no changes to medications and no restrictions to your normal activities.

5 Other relevant information about the research project

We are recruiting 130 patients for this study, with all patients. Of those 65 will be receiving Volatile and Opiate Anaesthetic and a further 65 will be receive Opiate-free TIVA. Researchers from The University of Melbourne and Austin Health are working in collaboration on this study

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 Austin Health.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. Other options are available; these include not participating. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

8 What are the possible benefits of taking part?

There will be no clear benefit to you from your participation in this research. You will be assisting in the knowledge of what is the best anaesthetic and pain management strategy for weight loss surgery.

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

We do not expect that participation in this study will cause any additional discomfort or increase the risk of adverse events for participants because both strategies are in active use within the department and they both work very well.

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

10 What will happen to my test samples?

We are not taking any extra blood or urine tests as part of this study. All we need to do is have a five minute chat once a day whilst you are in hospital.

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?

You should continue to use medications as advised by your clinician. Your participation in this research project will not alter the routine management of your medical condition/s.

13 What if I withdraw from this research project?

You are free to withdraw from the project at any time. Please notify a member of the research team before you withdraw to discuss any concerns you might have about the project

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 sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

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 lack of funding or decisions made by local regulatory / health authorities.

15 What happens when the research project ends?

After the project ends, you will have the routine care that is given to all patients after general surgery.

Once we have collected all information from all participants, the data will be analysed. The results of the study will then be published in scientific journal to enable other doctors and scientists to learn from the study. This may take up to 5 years. The main aim of this study is to understand how the anaesthetic helps prevent sickness and pain after weight loss surgery. As mentioned above the outcomes will be subtle so you will not notice much difference in this anaesthetic as to ones you have had before.

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. This will be done by coding patient information. The code will be stored securely so the information can be re-identified if necessary. All data will be analysed in a non-identifiable format. 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. Only pooled data will be published, not individual data. 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.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities, the institution relevant to this Participant Information Sheet, Austin Health or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

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

In accordance with relevant Australian and/or 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 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 have any complaints about any aspect of the project, you can use the contact information listed in Section 20 to report your concerns.

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.

18 Who is organising and funding the research?

The research is being conducted by Drs Douglas Hacking Justin Nazareth, Ranj Guha Daniel Banyasz and Kit James who are all in the Department of Anaesthesia in the department of Anaesthesia at Austin Health.

Funding for this project has been obtained from the Research funds within the Department of Anaesthetics.

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 Austin Health.

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 9496 3800 or any of the following people:

Clinical contact person

Name	Dr Douglas Hacking
Position	Staff Consultant Anaesthetist
Telephone	03 9496 5000
Email	Doug.HACKING@austin.org.au

Alternative clinical contact person

Name	Dr Justin Nazareth
Position	Joint Head of Peri-operative Medicine, Dept of Anaesthesia
Telephone	03 9496 5000
Email	justin.NAZARETH@austin.org.au

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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	Complaints Officer
Telephone	(03) 9496 4090 or (03) 9496 4035
Email	ethics@austin.org.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 name	Austin Human Research Ethics Committee
HREC Executive Officer	Mrs Lisa Pedro
Telephone	03 9496 4035 or 03 9496 4090
Email	ethics@austin.org.au

Reviewing HREC approving this research and HREC Executive Officer details

Local HREC Office contact (Single Site - Research Governance Officer)

Name	Ms Sharon Reid
Position	Research Governance Manager
Telephone	03 9496 2901
Email	rgo@austin.org.au

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Consent Form - *Adult providing own consent*

Austin Health

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Short Title	Opiate-free TIVA and Bariatric Surgery
Protocol Number	1
Coordinating Principal Investigator/	Dr Douglas Hacking
Associate Investigator(s)	Justin Nazarath, Ranj Guha, Daniel Banyasz & Kit James
Location	Austin Hospital

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 Austin Health 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.

Declaration by Participant – for participants who have read the information

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 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*

Austin Health

Title	**SOOThe**: **S**tudy of **O**besity-reduction and **O**piate-free **T**IVA
Short Title	Opiate-free TIVA and Bariatric Surgery
Protocol Number	1
Coordinating Principal Investigator/	Dr Douglas Hacking
Associate Investigator(s)	Justin Nazarath, Ranj Guha, Daniel Banyasz & Kit James
Location	Austin 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 Austin Health.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher† (please print) _____

Place Patient Label Here

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.