Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Title	ConsCIOUS-3: Noradrenergic Suppression to Reduce Connected Consciousness After Intubation- A randomised, placebo-controlled trial
Short Title	ConsCIOUS-3
Protocol Number	V1.4 dated 09.05.2022
Coordinating Principal Investigator/ Principal Investigator	Professor Robert Sanders
Location	Royal Prince Alfred 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 a healthy individual who is having surgery under general anaesthesia. The research project is testing to see how a commonly used sedative, Dexmedetomidine, affects levels of awareness and consciousness in individuals while under anaesthesia.

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. Your treating surgical team will be contacted during the recruitment process and will be informed of your participation, you will not be enrolled in the study if your surgical team does not support your involvement.

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?

The purpose of this pilot study is to determine if a commonly used sedative, Dexmedetomidine, may reduce changes in levels of consciousness during intubation (insertion of breathing tube). A pilot study is a small study used to test research protocol, recruitment strategies and feasibility of carrying out similar research on a larger scale.

Medications, drugs and devices have to be approved for use by the Australian Federal Government. Dexmedetomidine is approved in Australia by the Therapeutic Goods Administration for the use in procedural sedation. This study will be conducted under the Therapeutic Goods Administration (TGA) Clinical Trials Notification (CTN) Scheme. This allows the investigators to use this product for medical research purposes once the research has been assessed and approved by an authorised Human Research

This research has been initiated by the study doctor Professor Robert Sanders.

This project has been internally funded by the Royal Prince Alfred Hospital Department of Anaesthetics.

3 What does participation in this research involve?

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random).

You will be randomised to an intervention group or a placebo- the treating anaesthetist will be managing all medications during the general anaesthetic including the drug we are studying.

This study has been designed to collect data in objective manners and you will not be informed as to what study group you are enrolled.

As a patient undergoing surgery your participation will include the normal pre-anaesthetic assessments as well as some additional questions prior to surgery to assess medical history, anxiety levels, and medication use; and for females a questionnaire regarding menstruation and birth control.

During the general anaesthetic you may be asked to complete some easy tasks and answer basic questions- these will take place in the operating theatre as well as the recovery room.

Additionally you will be contacted at 24-hours and 7-days post-surgery to participate in a brief survey about your experience during your operation and your satisfaction with the anaesthetic and your experience.

Your participation in this study will not affect or change any of the medications you would normally be given, participation will add no more than 5 minutes to your expected procedure duration and it does not present any additional risk.

4 What do I have to do?

If you consent to participate in this research project you will be asked to follow the instructions provided to you prior to the day of surgery as part of standard care. These instructions will include what time you will be expected to arrive at hospital, fasting requirements including when you should stop drinking water prior to surgery and any changes you should make to taking normal medications. If you have any questions surrounding pre-operative preparation please contact The Perioperative Unit via Royal Prince Alfred switchboard on 02 9515 6111.

As a participant in the research project you will go into surgery as per normal and the study doctors will randomize you to a study group (please see above for more information). Prior to surgery you may be asked a few questions regarding your medical history, anxiety and medications, this pre-operative assessment will take less than 5 minutes.

During your surgery your vital signs will be monitored as part of standard procedures, in addition to these monitors a blood pressure cuff will be placed on your lower arm and inflated prior to anaesthetic. As you are falling asleep the study drug you have been allocated will be administered and your level of consciousness will be monitored and recorded. You will be given some basic commands during this time, such as '(NAME), squeeze my hand'. The cuff will be deflated after 20 minutes. The entire research procedure will take around 20 minutes and following this your anaesthetic and surgical procedure will continue as per normal.

After your surgery, a member of the research team will visit you 15 minutes post-operation and 60 minutes post-operation once you are in recovery. You will be asked a few questions about what you remember during your anaesthetic as well as some questions regarding pain and anxiety levels. Additionally a brief delirium assessment will be conducted to monitor sedation, agitation and confusion levels. These assessments will take around 15 minutes and will be completed during your stay in the recovery unit.

All other data collected will be de-identified and stored in secure locations for data analysis and use in for future research/education. As per legal guidelines these documents will be stored for a minimum of 15 years.

5 Other relevant information about the research project

This research project is recruiting 52 participants, all of who are between the ages of 18-40 and will be undergoing elective surgery.

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 Royal Prince Alfred 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 wish to participate you will undergo your planned surgery with no changes to care. Please note you may still receive the intervention drugs and have your levels of consciousness measured during your procedure (as per standard operating procedures) even if you do not participate in this study.

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 help to change and better provide anaesthetic care in the future.

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

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects related specifically to the use of the study drug Dexmedetomidine. As you will be under anaesthesia the treating doctor will treat any side effects such as hypotension (low blood pressure) or bradycardia (slow heart rate) with medications as per standard anaesthetic practice.

As you are undergoing a procedure, which requires anaesthesia, you will be informed prior to surgery of the risks associated with anaesthesia. Consent for the procedure and anaesthesia will be obtained by the treating team prior to your procedure. If you have any questions regarding the risks you can ask the treating team or anaesthetist.

Please note that anaesthesia is overall very safe and the most common problems associated with anaesthesia are feeling unwell or vomiting, bruising at the site of injections, sore throat or hoarse voice. Most patients do not have these problems. If these problems do happen, they usually get better very quickly. Damage to teeth may occur, but this is rare. The risk of brain damage or death due to anaesthesia is very rare.

The risk of problems from anaesthesia increases for patients who are having more major surgery, those with medical problems and those that require difficult anaesthetic procedures. Please note that these risks are associated with general anaesthesia and not related specifically to the research project. The risks specifically associated with this research project are minimal and you may experience some minor discomfort from the blood pressure cuff on your arm. This is no different to a normal blood pressure cuff which will be used routinely in theatres to measure your blood pressure at regular intervals. The blood pressure cuff will be removed after

20 minutes. There is a rare chance you may have a small bruise, numbness or tingling- these symptoms frequently improve quickly once the cuff is removed.

There are no risks associated with the EEG monitoring and the monitoring strip will be placed on your head in a comfortable manner.

Please note all medical staff involved in your procedure will adhere to confidentiality policies as per NSW Health. Research staff will ensure all information and data is protected.

There may be side effects that the researchers do not expect or do not know about and that may be serious – these may be linked directly to the study drug or could be associated with the your general anaesthetic/surgical procedure. Tell your treating medical team and study doctor immediately about any new or unusual symptoms that you get.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you.

Side Effect	How often is it likely to occur?	How severe might it be?	How long might it last?
Hypotension/Hypertension (low blood pressure/high blood pressure)	Occasional to Frequent	Moderate to Low Severity	1-3 hours
Bradycardia (slow heart rate)	Occasional to Frequent	Moderate to Low Severity	1-3 hours
Nausea/Vomiting	Infrequent to Rare	Moderate to Low Severity	1-3 hours
Dizziness	Occasional to frequent	Low severity	1-3 hours

10 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.

11 Can I have other treatments during this research project?

It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

12 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the 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.

13 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:
• Unacceptable side effects
• The drug/treatment/device being shown not to be effective
• The drug/treatment/device being shown to work and not need further testing

14 What happens when the research project ends?

Following the end of recruitment for this research project, data collected will be analysed by the research doctors and research team. Data collected during this research project will be used to determine the feasibility of a larger scale research project and some data may be published in academic works.

Part 2 How is the research project being conducted?

15 What will happen to information about me?

All data collected will be entered electronically and stored on a research database named RedCap (Research Electronic Data Capture). This is a secure, web-based, non-commercial, data management tool designed for research purposes, hosted and backed up on the Sydney Local Health District (SLHD) servers on a daily basis. No personnel other than researchers will have access to the research documents. The data will be analysed by the researchers at Royal Prince Alfred Hospital. The files will be retained for 15 years from the day the study is completed. Once this retention expires, the files will be disposed of using the SLHD confidential waste disposal service.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

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

16 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.

17 Who is organising and funding the research?

This research project is being conducted by Professor Robert Sanders and funded by the Department of Anaesthetics at Royal Prince Alfred Hospital.

18 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 Royal Prince 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.

19 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 02 9515 7460 or any of the following people

Clinical contact person

Name	*Professor Robert Sanders*
Position	*Principal Investigator*
Telephone	*02 9515 7460*
Email	*Robert.Sanders@sydney.edu.au*

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

The conduct of this study at RPAH has been authorised by the Sydney Local Health District. Any person with concerns or complains about the conduct of this study may also contact the Research Governance Office and quote protocol number X21-0410.	
Telephone	02 9515 7899
Email	SLHD-RPAEthics@health.nsw.gov.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Sydney Local Health District (RPAH Zone)
HREC Executive Officer	
Telephone	02 9515 6766
Email	SLHD-RPAEthics@health.nsw.gov.au

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

Name	Maree Larkin
Position	**Research Governance Officer**
Telephone	02 9515 7899
Email	SLHD-RPAEthics@health.nsw.gov.au

ConsCIOUS-3: Noradrenergic Suppression to Reduce Connected Consciousness after Intubation- a randomised, placebo-controlled trial

PARTICIPANT CONSENT FORM

I,_____ *[full name]*

Of_____
[address]

have read and understood the Participant Information Sheet on the abovenamed research study

and have discussed the study with
_____ [investigator responsible for conducting informed consent].

- I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers.

- I understand that a portion of the intra-operative assessment will be video-recorded, and will then be transcribed and be kept in a manner in which I cannot be identified for analysis and I agree to this.

- I understand that my participation in this study will allow the researchers and others, as described in the Information for Participants, to have access to my medical record, and I agree to this.

- I understand that my de-identified data may be used for future research and I agree to this.

- I would like to receive a copy of the study results when they become available. My email address

  is: _____

- I understand that, during the course of this study, my medical records may be accessed by regulatory authorities or by the Ethics Committee approving the research in order to verify results and determine that the study is being carried out correctly.

- I understand that the SLHD software license for REDCap (Research Electronic Data Capture) will be used to manage the collection and storage of my research data.

- I have had an opportunity to ask questions and I am satisfied with the answers I have received.

- I freely choose to participate in this study and understand that I can withdraw at any time.

- I consent to the future use of any data I provide for research purposes. I understand that before they can use any data I provide, they must seek additional ethics approval. YES/ NO
- I also understand that the research study is strictly confidential.
- I hereby agree to participate in this research study.
- I consent to the storage and use of my information collected from me for use, as described in the relevant section of the Participant Information Sheet, for:
  -This specific research project
  -Other research that is closely related to this research project
  -Any future research

Participant Name:_____-_____

Participant Signature:_____

Date:_____

Name of Person conducting informed consent:_____

Signature of Person conducting informed consent: _____

Date:_____