Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

The Alfred Hospital

Title	**A randomised controlled trial of high-flow nasal oxygen (HFNO) vs. standard oxygen therapy in patients undergoing transfemoral transcatheter aortic implantation**
Project Number	178/20
Project Sponsor	**Alfred Health**
Principal Investigator	**Dr Stuart Hastings**
Associate Investigator(s)	**Dr Chris Bain**
Location	**Alfred Health, Melbourne**

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you are undergoing a transfemoral transcatheter aortic valve implantation (TAVI) for your aortic stenosis. The research project is testing a oxygen delivery device. The new treatment is called High flow nasal oxygen (HFNO).

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 trial will investigate if high flow nasal oxygen (HFNO), a form of supplemental oxygen therapy which provides oxygen at higher flow rates than conventional oxygen delivery devices, to patients undergoing heart valve replacement under sedation results in improvements in patient outcomes.

HFNO is an established method of oxygen delivery for patients undergoing procedures under sedation, however its potential benefit has not yet been established for patients undergoing TAVI procedures.

This study aims to determine if HFNO results in a higher blood oxygen level. This study will also determine if HFNO results in increased patient comfort, decreased complications and a shorter length of hospital stay.

Medications, drugs and devices have to be approved for use by the Australian Federal Government through the Therapeutic Goods Administration (TGA). Optiflow thrive high flow nasal oxygen delivery devices are approved in Australia for administration of supplemental oxygen therapy for patients undergoing anaesthesia.

This research has been initiated by the study doctor, Dr Stuart Hastings. This research is sponsored by Alfred Health in Australia.

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 have a 50 per cent (1 in 2) chance of receiving HFNO or standard oxygen delivered via nasal prongs 2l/min. If you do not participate in the trial there is still a chance that you will receive either treatment.

Both the participants and the treating doctors will be aware of what oxygen therapy the participant is receiving.

In order to be included in this research project a number of steps will be taken:

- If you agree to be in the study you will need to sign the consent form at the end of this document prior to any assessments being performed
- You will be randomly be allocated to either receive
    - supplemental oxygen via standard methods (an oxygen mask) or
    - supplemental oxygen using the Optiflow HFNO device.
- During the procedure, a number of blood tests will be taken (from an arterial line which is routinely placed in the wrist of patients who are undergoing TAVI), and standard monitoring by the anaesthetic team will be applied, for example a blood pressure cuff.
- Study doctors and nurses will record the results during the procedure and participants will be asked questions following the procedure once they have recovered from their anaesthetic.
- Once you have been discharged from hospital, no more follow up visits or phone calls will be required. However, we will access your electronic medical records for 30 days.
- .

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. 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?

There are no additional requirements of patients to make any changes in their day to day lives in order to participate in this study.

5 Other relevant information about the research project

This study will be conducted at Alfred Health in conjunction with a similar study being conducted at The Royal Papworth Hospital, Cambridge, England. Data (which will not contain any information by which participants can be individually identified) will be shared between the two hospitals in order to increase the number of patients involved in the study.

This study aims to recruit 60 participants at Alfred Health over a one-year period.

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 Alfred 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 oxygen administration via standard methods (oxygen mask). 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?

We cannot guarantee or promise that you will receive any benefits from this research

However, possible benefits may include improved respiratory function, reduced respiratory complications, increased patient comfort during the procedures and a reduced requirement for a general anaesthetic during the procedure as well as a reduced length of hospital stay.

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.

HFNO as a form of supplemental oxygen therapy is a safe and effective method of administering additional oxygen to patients undergoing procedures under sedation. Side effects or adverse effects from the use of HFNO are incredibly rare.

Adverse effects include the potential for lung damage or changes in blood pressure. Patients who are at risk of these adverse effects will not be included in this study.

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.

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?

Collection of blood samples during the TAVI procedure is a standard occurrence in patients who are having this procedure. The blood taken for analysis during the procedure, as is standard practice, will be disposed of after the sample has been analysed. No blood or tissue samples will be stored as a part of this project.

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?

Yes. No limitations are placed on patients having other treatments during their involvement in this research project.

13 What if I withdraw from this research project?

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

14 Could this research project be stopped unexpectedly?

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

- Unacceptable side effects
- The device being shown not to be effective
- The device being shown to work and not need further testing

15 What happens when the research project ends?

The study treatment of supplemental oxygen via HFNO will only be available during the course of your procedure.

After your procedure is over and you are discharged from hospital, we will review your notes at 30 days to assess for any adverse events and incidence of infection.

Once the study is completed, data will be compiled, analysed and written into a journal article, with the view to publish this in a peer reviewed medical journal. Once completed, this publication will be available for review by both the general public and participants.

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.

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 and authorised representatives of the Sponsor, Alfred Health, the institution relevant to this Participant Information Sheet, Alfred Hospital, 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.

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.

In accordance with relevant Australian and State 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.

You will be assigned a study number. The data collected will be will be labelled with this study number and not your name or other identifiable information. The data collected with be “re-identifiable”, that is, the study doctor at the site where you were enrolled will be able to re-link your name with the study number, if necessary.

All data entered into the trial database will be coded, therefore maintaining patient privacy and confidentiality. This data will be stored indefinitely.

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. All paperwork data will be stored indefinitely. Electronic study records are stored in a locked database, on a locked computer, in a locked office.

Information about you may be obtained from your electronic health records up to 30 days after your procedure 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.

De-identified data will be shared with Papworth Hospital in the United Kingdom who have completed the same trail in patients. The data will be analysed and destroyed following the analysis in the United Kingdom.

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.

18 Who is organising and funding the research?

This research project is being conducted by Dr Stuart Hastings, Anaesthesiologist, Alfred Health. Fisher & Paykel will also be contributing to the study by providing the equipment and consumables. On completion of the study, Alfred Health will have ownership of these devices. 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 Alfred 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 9076 2000 or any of the following people:

Clinical contact person

Name	Stuart Hastings
Position	Staff specialist Anaesthetist, Department of Anaesthesiology and Perioperative Medicine, Alfred Health
Telephone	9076 3176
Email	s.hastings@alfred.org.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

Name	Complaints Officer
Position	Ethics and Research
Telephone	90763619
Email	research@alfred.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 approving this research and HREC Executive Officer details

Reviewing HREC name	Alfred Hospital Ethics Committee
Position	HREC Executive Officer
Telephone	9076 3619
Email	research@alfred.org.au

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Location	The Alfred

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 the Alfred 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 _____

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.

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

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Location	The Alfred

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 the Alfred.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Doctor/Senior Researcher†

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

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

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.