

St Vincent’s Hospital (Melbourne)

**Participant Information Consent Form**

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

*St.Vincent’s Hospital Melbourne*

|  |  |
| --- | --- |
| **Title** | The Use of Virtual Reality (VR) Environments in a Clinical Setting |
| **Short Title** | Virtual Reality |
| **Protocol Number** |  |
| **Principal Investigator** | Dr Peter Chan |
| **Associate Investigator(s)** | Simon Scharf |
| **Location** | St.Vincent’s Hospital Melbourne |

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

**1 Introduction**

You are invited to take part in the research project, “The Use of Virtual Reality (VR) Environments in a Clinical Setting”. This is because you match one of the recruitment criteria of good health,andare receiving a total knee or total hip replacement. The research project aims to assess a non-invasive method, of providing a calming environment via Virtual Reality Goggles on patients receiving joint replacement surgery under regional anaesthetic

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

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We are assessing a simple non-invasive method of providing a calming environment to patients and to assess side effects under while undergoing stressful medical procedures and minimizing the amount of sedation needed. The development of a simple virtual reality method could provide a better way of managing individuals both while undergoing surgery as well as in the Intensive Care by providing them with a calming environment that would facilitate their recovery.Feedback from your experience will guide our programming team to create better environments that can also be used for other research purposes including post traumatic stress disorder and pain management. The research has been initiated by the study doctor, Dr Peter Chan

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

A total of 50 people will participate in this study. They will consist of 2 groups. Twenty-five otherwise healthy volunteers receiving joint replacement surgery under regional anaesthetic will receive patient controlled sedation alone, and 25 patients receiving joint replacement surgery will receive patient controlled sedation combined with virtual reality therapy.

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

Participants will need to sign this consent form if they wish to participate in the study. Prior to your surgery, you will be randomized to receive patient controlled sedation alone, or patient controlled sedation with Virtual Reality therapy. Patient controlled sedation involves the use of a button which will provide you with a small amount of medication called propofol that will make you sleepy. You can push this button in the event of discomfort during your procedure to induce sleep. The button automatically prevents you from pushing the button too much, and you will remain monitored at all times by the anaesthetist looking after your anaesthetic. Virtual Reality Therapy will involve the use of a set of goggles that simulate a calming environment, coupled with calming music via noise cancelling headphones.

The simulation can be terminated at any time in the event of boredom or unpleasant side effects. Your vital signs and a measure of how sleepy you are, which are recorded as part of your surgery, will be documented. You will be asked to answer a short 5-minute survey before and after your experience during surgery

**Information collected from medical records**

Information related to any history of heart failure or infection in the body may be collected from your hospital records held at St Vincent’s Hospital Melbourne.

**Payment**

Unfortunately, there will be no remuneration associated with this project.

**5 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 St.Vincent’s Hospital Melbourne.

**6 What are the possible benefits of taking part?**

You may feel more calm and relaxed during your procedure by taking part.

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

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There have been some reported cases of nausea with the simulation, far less in intensity than what can be experienced on a day to day basis in the operating theatre or in the ICU.

8 Can I have other treatments during this research project?

Your participation in this research will not affect your other treatments.

9 Use of my information if I withdraw from the project

If you were to take part and then decided to leave the project, the researchers would like to keep the personal and/or health information about you that has been collected. This is to help them make sure that the results of the research can be measured properly. If you do not want them to do this, you must tell them before you withdraw from the research project.

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

If you are interested in a summary of the research findings please contact Dr Peter Chan (peter.chan@svha.org.au) Results will be available in 2016.

**11 What will happen to information about me?**

Any information obtained as part of this research project that can identify you will remain confidential and will only be used for the purpose of this research project. This information will only be disclosed with your permission, except as required by law.

Paper records are kept in locked offices with access restricted to study staff. Electronic information is stored on password protected computers with access restricted to study staff. Your information will be held securely for at least 15 years and then destroyed. Information about your participation in this research project may be recorded in your health records.

Your health records and any information obtained during the study are subject to inspection by the relevant authorities for the purpose of verifying the procedures and the data. These authorities include the Coordinating Principal Investigator and his delegates and St Vincent’s Hospital (Melbourne) Human Research Ethics Committee or as required by law. By signing the consent section you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities.

Results from this study will be discussed and/or published in peer-reviewed journals, conference presentations and other professional meetings. In any publication and/or presentation, information will be provided in such a way that you could not be identified, except with your permission.

**12 Can I access research information kept about me?**

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You could contact one of the researchers named below under the heading ‘Who can you contact?’ if you wanted to access your information.

**13 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.

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

This research project is being funded by the St. Vincent’s Research Endowment Fund and the St Vincent’s Catalyst Innovation Fund.

**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 St.Vincent’s Hospital Melbourne. 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.

*Information about this study*

If you wanted any more information about this project or if you had any medical problems which may be related to involvement in the project you could contact:

The Principal Investigator

Dr. Peter Chan

Intensive Care Unit, St Vincent’s Hospital (Melbourne)

Telephone: (03) 9231 4425, peter.chan@svha.org.au

Outside of usual business hours these staff can be contacted via St Vincent’s Hospital (Melbourne) switchboard on (03) 9231 2211.

*Complaints*

If you had any complaints about any aspect of the study or the way in which it is being conducted you could contact the Patient Liaison Officer at St Vincent’s Hospital (Melbourne) on Telephone: (03) 9231 3108. You will need to tell the Patient Liaison Officer the name of the Principal Investigator: Dr Peter Chan.

*Research Participant’s Rights*

If you had any questions about the rights of a research participant, then you could contact the Executive Officer Research at St Vincent’s Hospital (Melbourne) on Telephone: (03) 9231 3930.

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| **Principal Investigator** | Dr. Peter Chan |
| **Associate Investigator(s)** | Dr. Simon Scharf |
| **Location** | St.Vincent’s Hospital Melbourne |

**Declaration by Participant**

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 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 project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

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|  | | | | | | |
|  | 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.

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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.

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

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| **Location** | St.Vincent’s Hospital Melbourne |

**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 St.Vincent’s Hospital Melbourne.

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|  | | | | | | |
|  | 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.

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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.

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