Government of **Western Australia**
South Metropolitan Health Service

FIONA STANLEY hospital

Participant Information Sheet/Consent Form

Health/Social Science Research - *Adult providing own consent*

Fiona Stanley & Fremantle Hospital Group

Title	A Single Centre, Investigated-blinded, Randomized, Parallel-group, Superiority Pilot Study to Compare Traditional Training for Chest Drain Insertion to a Novel Immersive Virtual Reality Training Software Program.
Short Title	Virtual Reality Insertion of Chest-drain Outcomes Research
Protocol Number	*Version 1.3*
Project Sponsor	Innovation Leadership Group
Coordinating Principal Investigator/ Principal Investigator	*Dr Robert Swart*
Associate Investigator(s)	Chloe Goodred, Dr Andrew Lamb, Dr Neil Hauser, Dr James Anderson, Reuben Smith
Location	Fiona Stanley & Fremantle Hospital Group (FSFHG), Department of Anaesthesia & Pain Medicine, Level 2 Office 13.

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, entitled the Virtual Reality Insertion of Chest-drain Outcomes Research (VICTOR) study. The use of Virtual Reality (VR), as a clinical education tool, is increasing. The main objective of this research project is to compare the outcomes of traditional teaching methods against VR software training. The primary outcomes compared will include proficiency of chest drain insertion, adherence to the assessment checklist and the time taken to complete the task. A secondary objective will measure whether the use of VR software improves confidence levels related to the performance of chest drain insertion over traditional teaching methods.

Your contact details have been obtained from the anaesthetic department roster.

This *Participant Information Sheet/Consent Form* aims to inform you about what the research project entails, allowing you to make an informed decision as to whether you would like to participate or not.

Please read this information carefully. Ask questions about anything that you don't fully understand or would like more information on. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local health worker.

Participation in this research is entirely voluntary. If you do not wish to take part, you are under no obligation to do so. Consent forms will need to be signed by the participants prior to randomization and performance of any study assessment.
If you do decide that you would like to partake in the research project, you will be required to sign and complete 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 be involved in the research 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?

Emergency chest drain insertion under anaesthesia, is a rare but potentially lifesaving procedure. Due to the low likelihood of needing to perform this procedure it is difficult to become proficient and maintain the necessary skills. This, like other rare events, may have a negative effect on patient outcomes under general anaesthesia. Virtual reality, used as a simulation-based education tool, can provide an opportunity to learn how to safely insert a chest drain, without any inherent risk.

The aim of the project is to determine whether VR software can be used as an effective educational tool, for anaesthetic registrars, in the placement of a chest drain. This VR training software will be compared to a traditional teaching method of chest drain insertion. If the virtual reality education software is shown to be either superior or at least non-inferior to traditional training methods, it may then become a possible option to be incorporated in the anaesthetic training program. The chest drain program may also then be researched for application in other disciplines such as emergency medicine, surgery and intensive care.

This research project is been made possible through sponsorship by the Fiona Stanley & Fremantle Hospital Group Innovation Leadership Group and Vantari VR.

This research has been initiated by the researcher, *Dr Robert Swart*.

This research is sponsored in Australia by *Vantari VR*.

3 What does participation in this research involve?

The registrars from the FSFHG, Department of Anaesthesia & Pain Medicine will be asked to participate in this research project. Ineligibility criteria will be a history of severe discomfort with VR hardware use. Junior and senior anaesthetic registrars will be randomized in to either the control group (traditional teaching) or the intervention group (VR software training). The control group will receive traditional training in the form of a text based educational manual and an instructional video. The intervention group will complete the virtual reality training software program with a facilitator present. The facilitators role will be to provide orientation to the VR training program and to trouble shoot any technical issues with the software. Subsequent self-directed use of the virtual reality training software program will be possible. Similarly the control group will continue to have access to the instructional video.

Following completion of their respective training sessions, each participant will then perform a chest drain insertion on the SimMan 3G mannikin. The participants will be assessed by two assessors, blinded to group allocation, using a validated chest drain insertion checklist measuring competency, deviation from the prescribed checklist and time to task completion.

Participant confidence at performing chest drain insertion will be assessed using a pre and post assessment survey. Once the study is completed the control group will be offered the opportunity to complete the virtual reality training and the intervention group will be given access to the traditional training material.

The participants scores will be anonymised and kept on a password secure computer by the chief investigator. All training and assessment will take place within the FSFHG Department of Anaesthesia & Pain Medicine area, Clinical Room 13 Level 2.

There will be no remuneration or cost to the participants. The assessment on the SimMan 3G will not be recorded via video or audio.

If you decide to take part in this research project, you will be provided with a questionnaire to ascertain: 1) any prior VR training and 2) confidence in and ability to perform a chest drain insertion; this questionnaire will allow the researchers to determine your participation eligibility. Completing the questionnaire will take approximately 5mins.

If the screening questionnaire shows that you are eligible to participate, you will then be able to be included in the research project. If the screening questionnaire demonstrates that you are not suitable to participate in the research project, the research coordinator will discuss further options with you.

This research project has been designed to ensure that the researchers record and interpret the results in a fair and unbiased manner. There will be no input from any sponsors.

There are no costs associated with participating in this research project, nor will you be paid. However, you may receive reimbursement for any reasonable travel, parking, meals and other expenses associated with participating in the research project visit(s).

4 Other relevant information about the research project

The number of participants in the study will not be limited and all junior and senior registrars will be included provided they are deemed eligible to participate. This study is a collaboration between the FSFHG Department of Anaesthesia and Pain Medicine, Fiona Stanley Innovation Leadership Group and Vantari VR.

5 Do I have to take part in this research project?

Participation in any research project is entirely voluntary. If you do not wish to partake, you are not obliged to do so. If you do decide to take participate and later wish to withdraw your participation you are free to do so.

If you do decide to participate, you will be given required to take and sign a copy of the Participant Information and Consent Form.

Your decision whether to participate or not; to participate and then withdraw, will have no bearing on your relationship with professional staff and/ or your relationship with the FSFHG Department of Anaesthesia and Pain Medicine. Participation/non-participation will not affect the participant's professional advancement.

6 What are the possible benefits of taking part in this study?

There is no guarantee that participation in this research will ensure chest drain insertion competency nor is it an accredited training program or course. Potential benefits of participation may include exposure to an effective simulation-based education tool with the prospect of inclusion of VR being added to the training program in the future.

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

There are potential effects that have been described with the use of VR training. These include but are not limited to the following:
Headache
Nausea & associated vomiting
Claustrophobia
Dizziness

Participants may feel intimidated by the questions asked by investigators and this can be stressful or upsetting. If you do not wish to answer a particular question, you are entitled to skip that question and move on to the following question. You are also entitled to stop immediately and withdraw if you prefer. If you become upset or distressed as a result of your participation in the research project, the research team will arrange for counselling and/ or other necessary support. Any counselling or support will be provided by qualified staff that have no association with this research project. This counselling will be provided free of charge.

8 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team of your decision to withdraw. If you do withdraw, you will be asked to complete and sign a '*Withdrawal of Consent*' form; this will be provided to you by the research team.

If you decide to leave the research project, the researchers 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 up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

9 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons.

10 What happens when the research project ends?

The intent is for the study to be published in a journal and for the results to be presented at a future, yet to be determined, congress. The results will also be presented to all members of the FSFHG Department of Anaesthesia & Pain Medicine on one of the weekly Departmental academic meetings, date yet to be determined.

Part 2 How is the research project being conducted?

11 What will happen to information about me?

The assessment information will be anonymised and non-identifiable. All collected information will be password protected and managed only by the chief investigators. The information will be stored for 7 years. The data will only be used for this study and not passed on to any other 3rd parties.

By signing the consent form, you consent to the research team collecting and using personal information about you for the research project. The personal information that the research team will collect, and use relates only to the survey responses and assessment scores. Any information obtained in connection with this research project that can identify you will remain confidential. The participants assessment data will be de-identified and kept on a password protected computer database with limited investigator access only. 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.

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 it will be impossible to identify individual participants unless you have provided your express permission to do so. All the data will be presented in an anonymous nonidentifiable form.

In accordance with relevant Australian and/or Western Australian privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research 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.

12 Complaints and compensation

If you suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

In the event of loss or injury, or complications as a result of the research project, you should contact the study team as soon as possible. You will be assisted with arranging medical care if required. If you are eligible for Medicare you can receive any medical treatment required to create the injury or complication, free of charge, as a public patient in any Australian public hospital.

13 Who is organising and funding the research?

This research project is being conducted by Dr Robert Swart.

This research is sponsored in Australia by Vantari VR
It is being funded by Innovation Leadership Group.

Vantari VR may benefit financially from this research project if, for example, the project assists Vantari VR in any commercial enterprise.

You will not benefit financially from your involvement in this research project even if, for example, knowledge acquired from your information proves to be of commercial value to Vantari VR.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to Vantari VR, the researchers or their institutions, there will be no financial benefit to you or your family from these discoveries.

Fiona Stanley Hospital will receive a payment from Innovation Leadership Group for undertaking 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).

Vantari VR has contributed to sponsorship of this research project by providing the virtual reality software at no cost.

14 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 South Metropolitan Health Service Human Research Ethics Committee.
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.

15 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 problems which may be related to your involvement in the project, you can contact the researcher on *0497119754*

Research contact person

Name	*Robert Swart*
Position	*Anaesthetic Fellow*
Telephone	*0497119754*
Email	*Robswart6@gmail.com*

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	*Manager of the Research Support and Development Unit*
Position	*Manager of the Research Support and Development Unit*
Telephone	*(08)61523214*
Email	*Smhs.rgo@health.wa.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	South Metropolitan Health Service Human Research Ethics Committee
HREC Executive Officer	Ethics Coordinator
Telephone	08 6152 2064
Email	*smhs.hrec@health.wa.gov.au*

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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 care.

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

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by 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 Researcher† (please print) _____

Signature _____ Date _____

† An appropriately qualified 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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Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine care, or my relationships with the researchers or Fiona Stanley & Fremantle Hospital Group, Department of Anaesthesia & Pain.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

Declaration by 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 Researcher (please print) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide information concerning withdrawal from the research project.

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