PARTICIPANT INFORMATION SHEET AND CONSENT FORM

**The effects of virtual reality on pain intensity in people with cancer-related pain**

This study is being conducted by Professor Melanie Lovell and Dr Philip Austin of the Palliative Care Services at Greenwich Hospital and Professor Philip Siddall of the Pain Management services also at Greenwich Hospital. This study has been approved by the Northern Sydney Local Health District (NSLHD) Human Research Ethics Committee (HREC) under reference number 2019/ETH12454.

**Invitation**

You are invited to participate in this research project aimed at determining whether a virtual reality (VR) application results in a significant reduction in pain in people with cancer-related pain. This information sheet contains detailed information about the project. Once you understand what the project is about and if you agree to take part in it, you will be asked to sign a consent form. By signing the consent form, you indicate that you understand the information and that you agree to participate in the project. You will be given a copy of the information sheet and consent form to keep as your record.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. **‘What is the purpose of this study?’**
* We know that cancer-related pain is caused by the tumour pressing on bones, nerves and other tissues in the body. Cancer-related pain is also caused by cancer treatments where, for example, chemotherapy drugs may cause tingling or burning in your hands and feet.
* The aim of the study is to determine whether a virtual reality application results in a significant reduction in pain in people with cancer-related pain. We also aim to determine whether use of VR results in any change in negative pain related emotions.
1. **‘Why have I been invited to participate in this study?’**

You are eligible to participate in this study because you have had cancer-related pain for more than one month.

1. **‘What if I don’t want to take part in this study or if I want to withdraw later?’**

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

1. **‘What does this study involve?’**
2. Involvement in this study will require time independent of your routine clinical assessment
3. If you agree to participate in this study, you will be asked to sign this participant consent form. You will be required to attend for one visit of approximately three hours. You will complete five short questionnaires while researchers set up the VR (45 minutes).
4. You will undergo one of two types of application, either an immersive visual/audio VR experience where using a handheld device, move through an ambient countryside scene using a headset or the same VR application on a computer display for 15 minutes.
5. You will answer some of the same questionnaires
6. You will have a one-hour rest period in order to eliminate the effects of the first 15 minute VR application.
7. You will undergo the second of the two types of VR application, again for 15 minutes.
8. You will answer some of the same questionnaires plus a short interview about your VR experiences

This study will help us determine the effectiveness of VR in reducing pain in people with cancer pain using inexpensive and commercially available treatments that have minimal side-effects and that has the potential to benefit a large number of people with cancer-related pain.

1. **‘Where will the study take place?’**

The recruitment of participants will take place through clinical contact at the Greenwich Hospital. The experimental testing will take place at Greenwich Hospital

1. **‘How is this study being paid for?’**

The study is being funded by a grant obtained from Sydney Vital, an organisation whose objective is to take research from the laboratory bench and put into practice, and thus provide patients with access to the latest medical findings to improve patient-care and outcomes

1. **‘What are the alternatives to participating in this study?’**

If you decide not to participate in this study, and you wish to continue treatment, you will still receive the standard treatment available for your condition.

1. **‘Are there risks to me in taking part in this study?’**

Immersive VR may cause mild motion sickness, but is not harmful. You will have the opportunity to withdraw at any time if these sensations become intolerable.

1. **‘What happens if I suffer injury or complications as a result of the study?’**

If you suffer any injuries or complications as a result of this study, you should contact the study doctor as soon as possible, who will assist you in arranging appropriate medical treatment.

1. **‘Will I benefit from the study?’**

This is an exploratory study and as such, you may not receive benefit by taking part in this study. Our aims are to further medical knowledge that may help to improve future treatment and management of people with cancer pain. Data from this study will help in the development of non-pharmacological treatments for cancer-related pain.

1. **Will refreshments be available during the study?**

All participants will be offered refreshments i.e., water, tea and coffee etc. as a compensation for your time.

1. **Will taking part in this study cost me anything, and will I be paid?**

Participation in this study will not cost you anything and you will not be paid for participation in this study

1. **‘How will my confidentiality be protected?’**

Only those investigators named above will know whether or not you are participating inthis study. Any identifiable information collected about you in connectionwith this study will remain confidential and will be disclosed only with yourpermission, except as required by law. Only the researchers named above will have access to your details and results that will be storedsecurely in lockable cabinets at the Pain Management Services Department and password protected computers on Greenwich Hospital servers.

It is possible that your personal health records and information may be disclosed to other agencies such as the Northern Sydney Local Health District HREC and other government agencies. This will only occur when necessary and the provisions of Australian privacy law will be complied with. Your research information will be stored for a period of 15 years, after which paper will be shredded and destroyed and computer files securely deleted.

1. **‘What happens with the study results?’**

If you give us your permission by signing the consent document, we plan to discuss/publish the overall results in peer review journals, presentations at conferences or in other professional forums but in a form where you will not be personally identified.

1. **‘What should I do if I want to discuss this study further before I decide?’**

If you have any questions or concerns about your participation and involvement in the study you can contact **Dr Philip Austin** on **(02) 8878 3943**.

1. **‘Who should I contact if I have concerns about the conduct of this study?’**

This study has been approved by the Northern Sydney Local Health District (NSLHD) HREC. Any person with concerns or complaints about the conduct of this study should contact the Research Office who is nominated to receive complaints from research participants. If you need to contact the NSLHD you should contact them on **9926 4590** or contact them via email on nslhd-research@health.nsw.gov.au

**Thank you for taking the time to consider this study.**

**If you wish to take part in it, please sign the attached consent form.**

**This information sheet is for you to keep.**

CONSENT FORM

**Virtual-reality as a treatment for people with cancer-related pain**

1. I,................................................................................................................. of................................................................................................................

Agree to participate as a subject in the study described in the Participant Information Sheet set out above ***(or: attached to this form).***

1. I acknowledge that I have read the Participant Information Sheet, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.
2. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.
3. I understand that I can withdraw from the study at any time without prejudice to my relationship to Greenwich Hospital
4. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.
5. I understand that if I have any questions relating to my participation in this research, I may contact **Dr** **Philip Austin** on telephone **(02) 8878 3943** who will be happy to answer them.
6. I would like to receive published study findings on conclusion of the research **YES** **NO**
7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Sheet.

Complaints may be directed to the, Research Office, Phone **9926 4590**

# Signature of participant Please PRINT name Date

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# Signature of witness Please PRINT name Date

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# Signature of investigator Please PRINT name Date

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#### Palliative Care Services

**Greenwich Hospital, HammondCare**

# Virtual-reality as a treatment for pain in people with cancer-related pain

## REVOCATION OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with Greenwich Hospital or my medical attendants

Signature Date

Please PRINT Name

The section for Revocation of Consent should be forwarded to

Professor Melanie Lovell

Palliative Care Services,

Pallister House, Greenwich Hospital,

97-115 River Road, Greenwich,

NSW 2065