Subject: 2024/ETH01446: Application HREA - Approved \*\*ETHICS APPROVAL ONLY \*\*SITE SPECIFIC AUTHORISATION REQUIRED\*\*

From: no\_reply@regis.health.nsw.gov.au

**Date:** 7/08/2024, 10:35 am **To:** prof.alwin.chuan@gmail.com

Date of Decision Notification: **07 Aug 2024** 

Dear Dr Alwin Chuan.

Thank you for submitting the following Human Research Ethics Application (HREA) for HREC review;

2024/ETH01446: Using Virtual Reality to Reduce Procedural Anxiety before Surgery: A Non-Inferiority, Randomised Controlled Trial

This Application was reviewed as a **Greater than low risk review pathway** and was initially considered by the **South Western Sydney Local Health District Human Research Ethics Committee** at its meeting held on 15 Jul 2024.

The project was determined to meet the requirements of the National Statement on Ethical Conduct in Human Research (2023) and was **APPROVED**.

This email constitutes ethical and scientific approval only.

This project cannot proceed at any site until separate research governance authorisation has been obtained from the Institution at which the research will take place.

This project has been Approved to be conducted at the following sites:

#### Fairfield Hospital

The following documentation was reviewed and is included in this approval:

Documentation TitleVersionDateHuman Research Ethics ApplicationVersion 2.0 19.07.2024ProtocolVersion 2.0 23.07.2024MASTER Participant Information Sheet Version 2.0 23.07.2024MASTER Consent FormVersion 2.0 23.07.2024MASTER Case Report FormVersion 1.0 28.06.2024

<u>Application Documents</u> - (link will only be active for 14 days from the decision date. The approved documents are also available to download from forms section of this project in REGIS)

The Human Research Ethics Application reviewed by the HREC was:

Version: 1.01 Date: 23 Jul 2024

The approval is for a period of 5 years from the date of this e-mail (07 Aug 2024)

Please note the following conditions of approval:

# \*\*Condition of approval: Please ensure that the restrictions and social distancing for COVID-19 are followed until the restrictions have been lifted\*\*

- 1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including: any serious or unexpected adverse events; and unforeseen events that might affect continued ethical acceptability of the project.
- 1. The Principal Investigator will report proposed changes to the research protocol, conduct of the research, or length of HREC approval to the HREC in the specified format, for review. For multi-centre studies, the Chief Investigator should submit to the Lead HREC and then send the amendment approval letter to the investigators at each sites so that they can notify their Research Governance Officer.
- 1. The Principal Investigator will inform the HREC, giving reasons, if the project is discontinued before the expected date of completion.
- 1. The Principal Investigator will provide an annual report to the HREC and at completion of the study in the specified format.
- 1. The Principal Investigator must reassure participants about confidentiality of the data.
- 1. Proposed changes to the personnel involved in the study are submitted to the HREC accompanied by a CV where applicable.
- 1. The Principal Investigator is responsible for ensuring the research project is conducted in line with relevant NSW Health, South Western Sydney Local Health District and Hospital policies available from: <a href="https://www.swslhd.health.nsw.gov.au/ethics/policies.html">https://www.swslhd.health.nsw.gov.au/ethics/policies.html</a>

**Interpreter use:** If this study will involve the use of interpreters, you are required to contact SWSLHD Interpreter Services on 8738 6088 and/or <a href="mailto:swslhd-interpretersbookings@health.nsw.gov.au">swslhd-interpretersbookings@health.nsw.gov.au</a>. This is required even if you have access to interpreters for clinical purposes, as

SWSLHD Interpreter Services are required to review and approve the use of interpreters for any research work. Once you have contacted SWSLHD Interpreter Services, please ensure that you include the provided quote/s (if any) with your SSA submissions for your project.

Should you have any queries about your project please contact **our office** on the telephone number 8738 8304. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the SWSLHD website: <a href="https://www.swslhd.health.nsw.gov.au/ethics/">https://www.swslhd.health.nsw.gov.au/ethics/</a>

Please quote the above Ethics number in all correspondence. The HREC wishes you every success in your research.

Yours faithfully,

#### **Dr Cameron Lutman**

on behalf of

### **Professor Murray Killingsworth**

Chairperson, SWSLHD Human Research Ethics Committee

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007).* The processes used by this HREC to review multicentre research proposals have been certified by the National Health and Medical Research Council. Kindest Regards,

## Malina Peng

Research Ethics and Governance Coordinator | Research Directorate

South Western Sydney Local Health District (SWSLHD)

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Research Workshops: https://www.swslhd.health.nsw.gov.au/ethics/workshops.html

Name, position Mobile phone numbers

Dr. Cameron Lutman, Research Ethics and Governance Manager 0499 972 501

Ms. Malina Peng and Ms. Jia Ying Ooi, Research Ethics and Governance 0455 060 242 and 0418 114 563

Coordinators

Ms. Tayla Hibbs and Ms. Indiana Foerster, Research Ethics and

Governance Administrative Officers

0409 151 623 and 0400 181 958

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