Appendix 11.1.1: Version 1.1

Date 02/01/2023

PARTICIPANT INFORMATION SHEET

Prospective observational cross-over validation study of the CMR Virtual Reality headset for operating room configuration.

You are being invited to take part in a research project. Before you decide whether to take part, it is important for you to understand why the research is being undertaken and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Thank you for reading this.

1. What is the purpose of this research project?

Robotic Surgery is being introduced into Surgical training in Wales.
The Cambridge Medical Robotics' Versius system consists of an open console with a modular design, allowing for freedom of port placement Existing literature mostly addresses surgical skill, however the main difference of robotic surgery to laparoscopic surgery is the operating room setup and training required to achieve an efficient surgical robotic procedure with appropriately positioned bedside consoles.

The aim of the proposed research project is to determine the face and content validity of the e-learning and VR headset modules for efficiently and correctly setting up a operating-room robotic system.

Why have I been invited to take part?

You have been invited because you are a medical student with no prior robotic experience and have expressed a keen interest in Surgery. Your participation is invaluable in helping validate the training materials and integrate these into robotic training.

2. Do I have to take part?

No, your participation in this research project is entirely voluntary and it is up to you to decide whether to take part. If you decide to take part, the research project will be discussed with you, and you will be asked to sign a consent form. If you decide not to take part, you do not have to explain your reasons and it will not affect your legal rights.
You are free to withdraw your consent to participate in the research project at any time, without giving a reason, even after signing the consent form.

3. What will taking part involve?

You will be randomly assigned to one of two groups:

- The first group will complete a 10-module e-learning programme which educates the user to set up the CMR Robot in a theatre environment.
- The second group will complete 6 VR headset modules on a CMR virtual reality headset in your own time and space.

Both interventions take between 5-10 hours to complete, and you will be asked to complete these within a 2-week time frame.

Following these you will be given instruction and asked to set up the robotic system in theatre in the University Hospital of Wales. It is asked that you complete the modules as close to the assessment date as possible.

Your e-learning and VR headset scores will be saved and score sheets will be collected during your simulated setup sessions.

You may be asked during the set-up if you are happy for any photographs/videos to be taken, which may be used for visual demonstration during publicization of results, you are welcome to decline when completing the consent form, and again in person during the assessment.

4. Will I be paid for taking part?

No

5. What are the possible benefits of taking part?

There will be no direct advantages or benefits to you from taking part, but your contribution will help us in developing robotic training. Any possible publications resulting from this research will acknowledge participants as collaborators. You may request a certificate for taking part.

6. What are the possible risks of taking part?

There is a small risk of eye strain from using a VR headset for prolonged periods of time. This will be cautioned against in the participant information sheet. It will be suggested participants use the headset in a space free of any wires/objects as to not trip or collide with these in a virtual environment.

7. Will my taking part in this research project be kept confidential?

All information collected from (or about) you during the research project will be kept confidential and any personal information you provide will be managed in accordance with data protection legislation. Please see 'What will happen to my Personal Data?' (below) for further information.

8. What will happen to my Personal Data?

Cardiff University is the Data Controller and is committed to respecting and protecting your personal data in accordance with your expectations and Data Protection legislation. Further information about Data Protection, including:

- Your rights.
- The legal basis under which Cardiff University processes your personal data for research
- Cardiff University's Data Protection Policy
- How to contact the Cardiff University Data Protection Officer
- How to contact the Information Commissioner's Office

may be found at https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection

Consent forms will be retained for five years and may be accessed by members of the research team and, where necessary, by members of the University's governance and audit teams or by regulatory authorities. Anonymised information will be kept for a minimum of two years but

may be published in support of the research project and/or retained indefinitely, where it is likely to have continuing value for research purposes.

Note that it will not be possible to withdraw any anonymised data that has already been published or in some cases, where identifiers are irreversibly removed during the course of a research project, from the point at which it has been anonymised.

9. What happens to the data at the end of the research project?

Anonymised information will be kept for a minimum of five years but may be published in support of the research project and/or retained indefinitely, where it is likely to have continuing value for research purposes.

10. What will happen to the results of the research project?

It is our intention to publish the results of this research project in academic journals and present findings at conferences. Participants will not be identified in any report, publication or presentation.

11. What if there is a problem?

If you wish to complain or have grounds for concerns regarding any aspect of the manner in which you have been approached or treated during the course of this research, please contact Catherine Eley, or Dr Ned Powell, member of the Society of medicine Research Ethics Committee. If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, you may have grounds for legal action, but you may have to pay for it.

12. Who is organising and funding this research project?

The research is organised by Catherine Eley, through WIMAT in Cardiff University School of Medicine. The research is not receiving funding.

13. Who has reviewed this research project?

This research project has been reviewed and given a favourable opinion by the School of Medicine Research Ethics Committee, Cardiff University.

14. Further information and contact details

Should you have any questions relating to this research project, you may contact me during normal working hours:

Miss Catherine Eley Welsh Institute of Minimal Access Therapy (WIMAT) Cardiff Medicentre Cardiff CF14 4UJ Catherine.eley@hotmail.co.uk	Dr Ned Powell Cardiff University Society of medicine Research Ethics Committee (PowellNG@cardiff.ac.uk)

Thank you for considering taking part in this research project. If you decide to participate, you will be given a copy of the Participant Information Sheet and a signed consent form to keep for your records.

CONSENT FORM

Title of research project: **Prospective observational cross-over validation study of the CMR Virtual Reality headset for operating room configuration.**

SREC reference and committee: School of medicine

Name of Chief/Principal Investigator: Catherine Eley

	Please initial box
I confirm that I have read the information sheet dated 12/12/2022 version 1.0 for the above research project.	
I confirm that I have understood the information sheet dated 12/12/2020 version 1.0 for the above research project and that I have had the opportunity to ask questions and that these have been answered satisfactorily.	
I understand that my participation is voluntary and I am free to withdraw at any time without giving a reason and without any adverse consequences (e.g. to medical care or legal rights, if relevant). I understand that if I withdraw, information about me that has already been obtained may be kept by Cardiff University.	
I consent to the processing of my personal information (Name) for the purposes explained to me. I understand that such information will be held in accordance with all applicable data protection legislation and in strict confidence unless disclosure is required by law or professional obligation.	
I understand who will have access to personal information provided, how the data will be stored and what will happen to the data at the end of the research project.	
I understand that after the research project, anonymised data may be made publicly available via a data repository and may be used for purposes not related to this research project. I understand that it will not be possible to identify me from this data that is seen and used by other researchers, for ethically approved research projects, on the understanding that confidentiality will be maintained.	
I consent to being audio recorded/ video recorded/ having my photograph taken for the purposes of the research project and I understand how it will be used in the research.	
I understand how the findings and results of the research project will be written up and published.	

I agree to take part in this research project.	

Name of participant (print)	Date	Signature
Name of person taking consent (print)	Date	Signature

Role of person taking consent (print)

THANK YOU FOR PARTICIPATING IN OUR RESEARCH

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP