Minimal Risk Informed Consent Form for Participation in a Research Study – Residents and Medical Students

Study Title: Pandemic-Proofing Simulation-based Education: Development and Evaluation of Interactive Virtual Educational Content for Medical Trainees

OHSN-REB Number*:* 20210197-01H

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Funder(s): University of Ottawa Faculty of Medicine

INTRODUCTION

You are being invited to participate in our research study because you are a medical student interested in emergency medicine or an Emergency Medicine FRCPC resident. This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All of your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Please take your time in making your decision.

Taking part in this study is voluntary, it is your choice to participate. Deciding not to take part or deciding to leave the study later as well as the nature of your response will not result in any penalty, or impact on your evaluation or affect current or future health care or employment. You may decide to withdraw your consent to participate in this study at any point in time.

IS THERE A CONFLICT OF INTEREST?

There are no conflicts of interest to declare related to this study.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to develop and evaluate of two VR simulations (interactive VR, 360-degree VR video) applied to the context of Emergency Medicine. The aim of this pilot study is to develop two VR simulations, and to compare their effectiveness with traditional in-person theatre-based simulation. The study also looks to compare knowledge retention and application of knowledge during emergency crisis scenarios following VR-360, interactive VR, and theatre-based simulation sessions.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that about 45 residents and medical students will participate in this study.

This study should take about one year to complete and the results should be known in about 18 months.

WHAT WILL HAPPEN DURING THIS STUDY?

Prior to participating, you will be asked to complete a pre-test of your content-specific knowledge and knowledge application with respect to resuscitating a critically ill patient.

You will be equipped with a Polar H10 chest belt which will track your heart rate (HR) and heart rate variability (HRV). You will then participate in a video-recorded in-situ simulation of a patient resuscitation which will be scored.

After completion of your pre-test, you will be asked to participate in an evaluation of a VR model. Participants will be randomized to one of three groups – interactive VR, 360-degree video, or theatre-based education. This will be followed by a debriefing session either in person, if permitted, or remotely.

Two weeks later, all participants will complete a post-test of their knowledge and knowledge application, as well as participate in another in-situ simulated patient resuscitation. Once again, you will be wearing the Polar H10 which tracks HR and HRV, and once again, this session will be video-taped for scoring.

The information you provide is for research purposes only. You may choose to leave the study at any time.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

Your active participation will last approximately 4 hours over three sessions. Your three sessions will be completed over a two-week period. Your participation will consist of a pre-test and in-situ simulation involving resuscitation of a critically ill patient, followed by randomization to either an *in situ* simulation, 360-degree VR or interactive VR session and de-brief activity. Two weeks later, you will complete a post-test gauging your knowledge and knowledge application and participate in another in-situ patient resuscitation simulation.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the research team.

You may withdraw your permission to use information that was collected about you for this study at any time by letting the research team know. However, this would also mean that you withdraw from the study.

If you withdraw consent after completing the VR sessions or in-situ simulations, please inform the research assistant so that your data can be removed from the analysis pool.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

There are no risks to you from participating in this study but taking part in the live and VR scenarios could prove stressful and possibly mentally exhausting. You may stop your participation at any time if

you have these feelings.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

You may not receive direct benefit from participating in this study. Participation in this study may help build an effective VR simulation to assess and assist training in Emergency Medicine.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the research team will only collect the information they need for this study.

Records identifying you at this centre will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

- The Ottawa Health Science Network Research Ethics Board who oversees the ethical conduct of this study in Ottawa
- The Ottawa Hospital, to oversee the conduct of research at this location

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. De-identified data will be shared with members of the study team at Sunnybrook Health Sciences Centre for analysis.Your name, address, or other information that may directly identify you will not be used. The records received by these organizations may contain your unique participant ID. Assigning a unique study ID lowers the risk that the data collected can be linked back to you.

Video recordings of in-situ simulation will be used only for scoring purposes on the study. Recordings will only be seen by the study team and the two raters. Video recordings will be kept on a secure server. They will be deleted from the devices they were initially recorded on.

Communication via e-mail is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be used in analyses and will be published/ presented to the scientific community at meetings and in journals.

Your de-identified data from this study may be used for other research purposes. If your study data is shared with other researchers, information that links your study data directly to you will not be shared.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

WHAT IS THE COST TO PARTICIPANTS?

Participation in this study will not involve any additional costs to you.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

You will not be paid for taking part in this study.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please contact the research team.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form, you do not give up any of your legal rights against the researcher or involved institutions for compensation, nor does this form relieve the researcher or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study you can talk to your study doctor, or the doctor who oversees the study at this institution. That person is:

Dr. Glenn Posner	613-721-2907
Principal Investigator Name	Telephone

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. Please contact The Ottawa Health Science Network Research Ethics Board, Chairperson at 613-798-5555 extension 16719.

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SIGNATURES

- All my questions have been answered,
- I understand the information within this informed consent form,
- I have read, or someone has read to me, each page of this participant informed consent form,
- I do not give up any of my legal rights by signing this consent form,
- I agree to take part in this study.

Signature of Participant	Printed Name	Date

Investigator or Delegate Statement
I have carefully explained the study to the study participant. To the best of my knowledge, the participant understands the nature, demands, risks and benefits involved in taking part in this study.

Signature of Person Conducting the Consent Discussion	Printed Name and Role	Date