

Hamilton Integrated Research Ethics Board AMENDMENT REQUEST

REB Project #: 11-409

Principal Investigator: Dr. Geoff Norman
Dr. Lawrence Grierson

Project Title: Studies of Learning and Reasoning in Medicine

SUB-STUDY: Observational Practice and Educational Networking: Extending the Simulation-based Education beyond the Simulation Laboratory

Document(s) Amended with version # and date:

- Administrative Change - Add Sub-study: Observational Practice and Educational Networking: Extending the Simulation-based Education beyond the Simulation Laboratory
- Administrative Change - Dr. Lawrence Grierson is the Principal Investigator of this Sub-study
- Consent Form - Letter of Information/Consent Dated: 17 November, 2014
- Other - Synopsis of this Sub-study

Research Ethics Board Review
(this box to be completed by HIREB Chair only)

☒ Amendment approved as submitted

☐ Amendment approved conditional on changes noted in "Conditions" section below

☐ New enrolment suspended

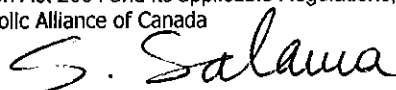
☐ Study suspended pending further review

Level of Review:

☐ Full Research Ethics Board

☒ Research Ethics Board Executive

The Hamilton Integrated Research Ethics Board operates in compliance with and is constituted in accordance with the requirements of: The Tri-Council Policy Statement on Ethical Conduct of Research Involving Humans; The International Conference on Harmonization of Good Clinical Practices; Part C Division 5 of the Food and Drug Regulations of Health Canada, and the provisions of the Ontario Personal Health Information Protection Act 2004 and its applicable Regulations; For studies conducted at St. Joseph's Hospital, HIREB complies with the health ethics guide of the Catholic Alliance of Canada



Suzette Salama PhD., Chair
Raelene Rathbone, MB BS, MD, PhD, Chair

11/18/2014
Date



Program for Educational Research & Development

Faculty of Health Sciences
Michael G. DeGroote Centre
for Learning and Discovery
Juravinski ERDC, Room 3510
1200 Main Street West
Hamilton, ON, Canada L8N 3Z5

Phone: 905-525-9140 x23114
Fax: 905-572-7099
Email: perd@mcmaster.ca
<http://www.fhs.mcmaster.ca/perd>



November 17th, 2014

LETTER OF INFORMATION / CONSENT

**Observational Practice and Educational Networking: Extending
the Simulation-based
Education beyond the Simulation Laboratory**

Investigators:

Principal Investigator

Dr. Lawrence Grierson
Department of Family Medicine
McMaster University
Hamilton, Ontario, Canada
(905) 525-9140 ext. 28503
E-mail: griersle@mcmaster.ca

Student Investigator

Arthur Welsher
Department of Kinesiology
McMaster University
E-mail: arthur_welsher10@hotmail.com

Purpose of the Study

This study will generate theoretical knowledge concerning the optimal application of video-based observational practice and educational networking approaches to simulation-based learning. It will also further develop, expand and improve an innovative, internet-mediated Observational Practice and Educational Networking (OPEN) system. This work will also expand our knowledge of simulation-based education and its impact in a distributed health profession education context.

Procedures involved in the Research

If you choose to participate in this study, you will be asked to attempt the elliptical excision skill in a simulation-based performance context, participate in a 14-day

online, observational learning period, and then perform attempts of the simulated elliptical excision after the 2-week intervention, and again one month later. Prior to your first attempt, you will view a standard and error-free instructional video performed by a general surgeon that will demonstrate the correct elliptical excision (EE) procedure. After this attempt, you will then be allocated to an experimental group and given access to the OPEN system for 14 days where you are asked to view and assess 8 videos attempts of the EE procedure (approx.. one every other day).

Potential Harms, Risks or Discomforts:

There are no potential harms or risks associated with your participation in this study.

Potential Benefits

There are no direct benefits associated with your participation in this study. However, this work will assist the scientific community's understanding of observational learning in health professions education. It will contribute to the development of an effective and flexible observational practice and education networking learning environment.

Payment or Reimbursement

At the end of the experimental portion of the study, participants will be provided an opportunity to participate in an EE workshop that will be run by an experienced surgical resident.

Confidentiality

You are participating in this study confidentially. We will not use your name or any information that can be used to identify you. All electronic data will be anonymized, coded and stored on a password protected computer. This computer and all hard copy documentation (i.e., signed consent forms) will be kept secure in Dr. Grierson's office (MDCL 3522) for 3 years following the completion of the project, after which time it will be destroyed. The data will only be seen by Arthur Welsher and Dr. Grierson. As soon as consent forms are signed and data is collected it will be immediately taken to Dr. Grierson's office and appropriately stored. If the results are published, no names or identifying information will be released or published.

Participation and Withdrawal

Your participation in this study is voluntary and it is your choice to be part of the study or not. If you decide to be part of the study, you can decide to stop (withdraw), at any time, even after signing the consent form or part-way through the study. If you decide to withdraw, there will be no consequences to you. In

cases of withdrawal, any data you have provided will be destroyed unless you indicate otherwise.

Information about the Study Results

We expect this study to be completed by approximately March 2015. You may request a summary of the results after April 1st, 2015.

Questions about the Study

If you have questions or need more information about the study itself, please contact me at:

Arthur Welsher (student investigator): arthur_welsher10@hotmail.com or 289 922-9232

For further information, contact Lawrence Grierson, Principal Investigator at 905-525-9140 ext 22738.

If you have any questions regarding your rights as a research participant you can contact the Office of the Chair of the Hamilton Integrated Research Ethics Board at 905 521-2100, Ext. 42013.

CONSENT

I have read the information presented in the information letter about a study being conducted by ____ of McMaster University.
I have had the opportunity to ask questions about my involvement in this study and to receive additional details I requested.
I understand that if I agree to participate in this study, I may withdraw from the study at any time. I have been given a copy of this form. I agree to participate in the study.

Name of Participant

Signature of Participant

Date

Consent form administered and explained in person by:

Name

Signature

Date

