



## Graduate Diploma in Health Research PROGRAM – 2018

### SUPERVISOR & PROJECT INFORMATION FORM

Please complete and return via email only ([gdip.hres@utoronto.ca](mailto:gdip.hres@utoronto.ca)) by **September 4, 2018**  
(forms received after this date will not be posted).

#### Supervisor Information

**Name:** Dr. Rob Fowler

**Email:** [robfowler@sunnybrook.ca](mailto:robfowler@sunnybrook.ca)

**Degree(s):** MDCM, MS

**SGS Department:** IHPME

**Academic Rank:** Professor

**Field of Research:** Clinical Epidemiology

**Research Institution Affiliation (if applicable):** Sunnybrook Research Institute

**Allocation of student contact time:** 10(number of hours per week YOU are available to the student for any concerns or to review progress)

**Project Information** (for posting on GDipHR website)

**Title:** Establishing the feasibility and safety of providing critical care to patients with Ebola through design of a simulated Ebola Treatment Unit.

**Introduction**

Ebola Virus Disease (EVD) is a highly contagious zoonosis with documented case fatality rates of up to 90% in humans (1). The provision of basic and advanced medical care was not routinely available in countries affected by EVD during the 2014-2016 West Africa outbreak. Over the course of the outbreak, as systems of care became more organised and medical interventions increased, the case-fatality rate dropped from 70% to 40% (2-3). Understanding the feasibility and barriers to the application of basic and advanced clinical support is important to improving care in future outbreaks.

**Objective**

To explore the feasibility and safety of delivering advanced medical care to patients in a simulated Ebola Treatment Unit (ETU) under two climatic conditions; i.e. 'hot': temperature of 35° C, 60% relative humidity; and 'cool': temperature of 20° C, 20% relative humidity.

**Hypothesis**

To test whether it is feasible and safe for healthcare workers wearing personal protective equipment (PPE) to provide advanced supportive care to severely ill patients in a simulated ETU under austere (hot and humid) conditions.

**Methods**

Study Design:

We will run a pilot study involving 10-15 volunteer health care workers (HCWs), this will help refine the study protocol. We will then conduct the main study with a goal of recruiting 75-100 volunteers, each volunteer will be randomized to perform advanced clinical procedures in any one of the 2 climatic conditions. All procedures and data collection will be done at the Defence Research and Development Canada (DRDC), Toronto Ontario.

Study population:

Health care workers (i.e. physicians, physician assistants, nurses, respiratory therapists, and paramedics) between the ages of 18-60 years.

Exclusion criteria: 1. Any health care worker who is deemed unfit on medical grounds by the physical readiness assessment questionnaire (PAR-Q form) and corroborated as such by the principal investigators. 2. Female HCWs who are pregnant.

### Study procedure:

Healthcare workers will be recruited by either word of mouth, or via emails, or through their institutions and professional groups. Prior to study day, all participants will be provided with a study information package and asked to do the following tasks: fill in a medical fitness checklist (physical assessment and readiness questionnaire-PAR Q; read and sign the consent form; fill in the pre-simulation questionnaire and watch the instructional videos of the procedures.

Study procedures include: 1. Donning and Doffing of personal protective equipment (PPE) in accordance to World Health Organization protocols (4), 2. Inserting of a peripheral venous catheter, 3. Inserting a mid-line arm peripheral venous catheter, and 4. Endotracheal intubation. All these medical tasks will be performed on simulated patient mannequins.

### Participant safety, performance and data collection:

On the study day, the study team will monitor participants': heart rate (HR), systolic and diastolic blood pressure (SBP, DBP) and pulse rate, respiratory rate (RR), oxygen saturation, tympanic temperature, skin temperature, weight and height.

After donning PPE, participants will be led to the climatic chamber where patient histories will be provided via an audio headset and then thereafter asked to perform tasks accordingly. Participant performance will be measured according to a task-specific checklist, task duration, and total number of PPE breaches and near-miss incidents. During the simulation, vital signs will be measured every 10 minutes. The threshold values for simulation cessation are a HR > 85% of HR max or < 40 bpm, SBP < 90 mmHg or >180 mmHg or a drop > 40 mmHg below baseline SBP and a self-rated thermal comfort scale of  $\geq 12$ . Participants will be asked to fill in a post-simulation questionnaire with a variety of close, open and Likert-type questions.

Two trained study personnel will independently collect data using a case report form-CRF, agreement will be reached with the help of video recordings, and the raw data will be uploaded to REDCap and SAS (Version 9.3) for analysis.

### Research Ethics:

This study has received REB approval from Sunnybrook Health Sciences Centre (SHSC) and Defence Research and Development Canada (DRDC) under protocol numbers 130-2017 and 2018-002 respectively. Informed consent will be sought from all the participants.

### **Budget/Funding.**

This study has received funding from the Canadian Institutes of Health Research (CIHR).

**Schedule and timeline.**

Activity	2018				2019				2020	
	1 <sup>st</sup> Quarter	2 <sup>nd</sup> Quarter	3 <sup>rd</sup> Quarter	4 <sup>th</sup> Quarter	1 <sup>st</sup> Quarter	2 <sup>nd</sup> Quarter	3 <sup>rd</sup> Quarter	4 <sup>th</sup> Quarter	1 <sup>st</sup> Quarter	2 <sup>nd</sup> Quarter
Protocol Submission and REB clearance	X	X								
Pilot study		X	X	X						
Review of Pilot findings			X	X						
Dissemination of findings to scholarly audiences			X	X						
Main study				X	X	X	X	X	X	X
Data Analysis and Manuscript writing						X	X	X	X	X
Dissemination of findings to scholarly audiences through oral presentations, abstract submissions and research articles								X	X	X

**Benefits.**

1. We aim to establish the feasibility of administering advanced supportive care in ETUs and evaluate safety to healthcare workers in controlled simulated conditions given the limited data available (5).
2. Volunteers will have an opportunity to practice procedures that they may be called upon to do in real-life, including caring for patients while wearing personal protective equipment.
3. Using the study findings, the research team will develop feasible, safe patient-care ETU principles and recommendations for dissemination in traditional scientific outlets and consideration by care partners field-testing and live implementation in future outbreaks.

### Description of Research Personnel.

This is a multi-site collaborative project led by primary investigators from SHSC who are critical care specialists with frontline experience in managing EVD patients, a senior applied physiologist co-investigator from DRDC and a technical team composed of; physicians with experience diagnosing and treating infectious diseases, physiologists, pharmacist and a summer student.

### References.

1. Bah EI, Lamah MC, Fletcher T, Jacob ST, Brett-Major DM, Sall AA, Shindo N, Fischer WA, Lamontagne F, Saliou SM, Bausch DG et al. Clinical presentation of patients with Ebola virus disease in Conakry, Guinea. *New England Journal of Medicine*. 2015;372(1):40-7.
2. Schieffelin JS, Shaffer JG, Goba A, Gbakie M, Gire SK, Colubri A, Sealfon RS, Kanneh L, Moigboi A, Momoh M, Fullah M et al. Clinical illness and outcomes in patients with Ebola in Sierra Leone. *New England Journal of Medicine*. 2014;371(22):2092-100.
3. Ansumana R, Jacobsen KH, Idris MB, Bangura H, Boie-Jalloh M, Lamin JM, Sesay S, Sahr F et al. Ebola in Freetown area, Sierra Leone—a case study of 581 patients. *New England Journal of Medicine*. 2015 Feb 5;372(6):587-8.
4. World Health Organization. How to put on and how to remove personal protective equipment posters. January 2015. <http://www.who.int/csr/resources/publications/ebola/ppe-steps/en/>
5. Grélot L, Koulibaly F, Maugey N, Janvier F, Foissaud V, Aletti M, Savini H, Cotte J, Dampierre H, Granier H, Carmoi T. Moderate thermal strain in healthcare workers wearing personal protective equipment during treatment and care activities in the context of the 2014 Ebola virus disease outbreak. *The Journal of infectious diseases*. 2015 Dec 9;213(9):1462-5.

If human subjects are involved, have the appropriate Research Ethics Board approvals been obtained?

YES  NO  Application Submitted  N/A

Do you expect this work will be published within the 20 months?

YES  NO  Uncertain (but the student will have the ability to prepare aspects of the work for scholarly presentations in abstract form, with full publications and manuscripts following.

**Student's roles and responsibilities (please be as specific as possible):**

- Become familiar and comfortable with all experimental procedures for the main trial.
- Prepare a sub-study that is student specific, to accompany the main trial.
- Develop, with assistance from the investigators and project biostatistician, the analytic plan for the sub-study
- Carry out the sub-study with the research team.
- Assist with data collection during the participant simulation sessions for the main and sub-study
- Assist with data input in the database (REDCap) and perform some data analysis, with supervision for the main and sub-study.
- Assist with study site preparation before participant arrival i.e. setting up procedure tasks (PPE doffing and donning stations, peripheral venous catheter insertion station, mid-line arm peripheral venous catheter insertion and intubation stations), activating physiological equipment (Equivital chest Unit, skin thermistors and thermobuttons etc.) and document preparation (consent forms, PAR-Q forms, Case Reporting Forms-CRFs and pre/post simulation questionnaires).
- Assist with abstract and manuscript writing for submission to scholarly journals.
- Prepare a student-led abstract and manuscript for submission to scholarly journals.

*Please indicate who will serve as the student's direct report for daily oversight (PI, PhD student, technician, etc...): PI and Project Manager*