



Queen's University Health Sciences & Affiliated Teaching Hospitals Research Ethics Board (HSREB)

HSREB Initial Ethics Clearance

April 17, 2020

Dr. Brooke Linden
Centre for Health Services and Policy Research
Queen's University

TRAQ #: 6029173

Department Code: HSPR-0010-20

Study Title: "HSPR-0010-20: Cross-Canada Multi-site Evaluation of the Post-Secondary Student Stressors Index (PSSI)"

Supervisor: Dr. Heather Lee Stuart

Review Type: Delegated

Date Ethics Clearance Issued: April 17, 2020

Ethics Clearance Expiry Date: April 17, 2021

Dear Dr. Linden:

The Queen's University Health Sciences & Affiliated Teaching Hospitals Research Ethics Board (HSREB) has reviewed the application and granted ethics clearance for the documents listed below. Ethics clearance is granted until the expiration date noted above.

Document Name	Comments	Version Date
Letter of Information	LOI English	2020/04/16
Letter of Information	LOI French	2020/04/16
Survey	Survey French	2020/04/16
Survey	Survey English	2020/04/16
Recruitment Letter/Email/Notice/Poster	Recruit French	2020/04/16
Recruitment Letter/Email/Notice/Poster	Recruit English	2020/04/16
Supervisor's letter/ e-mail	Supervisor Letter	2020/03/02

Documents Acknowledged:

- Ethics training certificates: Linden and Stuart
- CV: Linden and Stuart

Amendments: No deviation from, or changes to the protocol, informed consent form and conduct of study should be initiated without prior written clearance or an appropriate amendment from the HSREB, except when necessary to eliminate immediate hazard(s) to study participants or when the change(s) involves only administrative or logistical aspects of the study.

Renewals: An annual renewal event form or a study closure event form must be submitted annually as per the TCPS 2 Article 6.14. As a courtesy, the Office of Research Ethics may send reminders 30 days in advance of the ethics clearance expiry date. All lapses in ethics clearance will be documented on the annual renewal clearance letter.

Suspension letters may be issued for lapses in ethics clearances one day or greater, with subsequent termination and closure of the ethics file for lapses greater than 10 business days. Terminations should be reported to applicable regulatory authorities (e.g., Health Canada, FDA).

Completion/Termination: The HSREB must be notified of the completion or termination of this study through the submission of a study closure event in TRAQ.

Reporting of Serious Adverse Events: Any unexpected serious adverse events occurring locally must be reported within 2 working days or earlier if required by the study sponsor. All other serious adverse events must be reported within 15 days after becoming aware of the information.

Reporting of Complaints: Any complaints made by participants or persons acting on behalf of participants must be reported to the Research Ethics Board within 7 days of becoming aware of the complaint.

Note: All documents supplied to participants must have the contact information for the Research Ethics Board.

Investigators please note that if your study is registered by the sponsor, you must take responsibility to ensure that the registration information is accurate and complete.

Given the public health emergency related to COVID-19 we are requesting that researchers **proposing in-person contact and/or in-person research with communities** do not initiate in-person data collection until this public health emergency is over. Modifications should be made to eliminate in-person (e.g., conduct interviews, focus groups remotely, on-line surveys, etc.) if possible.

If the research study is providing an essential treatment option that is absolutely necessary for the welfare of the participant(s) a request for exemption will be required. Exemption requests need to be vetted by Jennifer Couture, Manager, Research Ethics Compliance, (Jennifer.couture@queensu.ca) to bring forward to the appropriate REB Chair for consideration.

New ethics applications that **do propose in-person contact will only be granted a conditional ethics clearance.** Conditional ethics clearance means your study has received ethics clearance but **you do not have permission to start in-person data collection until COVID-19 research restrictions are removed and you receive an updated ethics clearance letter.** Other aspects of the research not involving in-person contact may start once conditional clearance is issued (e.g., secondary data review, remote survey).

As greater clarification on risks of COVID-19 spread and risk of infection is provided by Queen's University and our Public Health partners, these restrictions will be re-assessed. Please visit <https://www.queensu.ca/vpr/covid-19> for the most up to date information on the COVID-19 Outbreak and its Impact on Queen's University Research.

Regards,



Albert F. Clark, PhD

Chair, Queen's University Health Sciences and Affiliated Teaching Hospitals Ethics Board

The HSREB operates in compliance with, and is constituted in accordance with, the requirements of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2); the international Conference on Harmonisation Good Clinical Practice Consolidated Guideline (ICH GCP); Part C, Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Product Regulations; Part 3 of the Medical Devices Regulations, and the provisions of the Ontario Personal Health Information Protection Act (PHIPA 2004) and its applicable regulations. The HSREB is qualified through the CTO REB Qualification Program and is registered with the U.S. Department of Health

and Human Services (DHHS) Office for Human Research Protection (OHRP). Federalwide Assurance Number: FWA#: 00004184, IRB#: 00001173. HSREB members involved in the research project do not participate in the review, discussion or decision.