

Conjoint Health Research Ethics Board Research Services Office 2500 University Drive, NW Calgary AB T2N 1N4 Telephone: (403) 220-2297 chreb@ucalgary.ca

CERTIFICATION OF INSTITUTIONAL ETHICS APPROVAL

The Conjoint Health Research Ethics Board (CHREB), University of Calgary has reviewed and approved the following research protocol:

Ethics ID: REB18-1770

Principal Investigator: Thomas Stelfox

Co-Investigator(s): Kirsten Fiest

Christopher Grant Jayna Holroyd-Leduc

Daniel Niven

Jeanna Parsons Leigh Danijela Piskulic Andrea Soo Danny Zuege

Student Co-Investigator(s): There are no items to display

Study Title: Development of a Patient-Oriented Care Transitions Bundle for Critically Ill

Patients in the Intensive Care Unit (ICU)

Sponsor: Critical Care Strategic Clinical Network

Canadian Foundation for Healthcare Improvement

Effective: January 2, 2019 Expires: January 2, 2020

This study has been reviewed by the full Conjoint Health Research Ethics Board of the University of Calgary on December 06, 2018.

The following documents have been approved for use:

- Caregiver Informed Consent Form, 2.0, December 18, 2018
- Surrogate Informed Consent Form, 2.0, December 18, 2018
- Patient Informed Consent Form, 2.0, December 18, 2018
- Regained Capacity Consent Form, 2.0, December 18, 2018
- Patient Survey, 1.0, November 13, 2018
- Patient Demographic Form, 1.0, November 13, 2018
- Caregiver Survey, 1.0, November 13, 2018
- Caregiver Demographic Form, 1.0, November 13, 2018
- Protocol, 3.0, December 13, 2018

The CHREB is constituted and operates in accordance with the current version of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS); International Conference on Harmonization E6: Good Clinical Practice Guidelines (ICH-GCP); Part C, Division 5 of the Food and Drug regulations, Part 4 of the Natural Health Product Regulations and the Medical Device Regulations of Health Canada; Alberta's Health Information Act, RSA 2000 cH-5; and US Federal Regulations 45 CFR part 46, 21 CFR part 50 and 56.

You and your co-investigators are not members of the CHREB and did not participate in review or voting on this study.

A waiver of consent was granted for access to personal identifiable health information consistent with the conditions under section 50, Health Information Act of Alberta.

Restrictions:

This Certification is subject to the following conditions:

- 1. Approval is granted only for the research and purposes described in the application.
- 2. Any modification to the approved research must be submitted to the CHREB for approval.
- 3. An annual application for renewal of ethics certification must be submitted and approved by the above expiry date.
- 4. A closure request must be sent to the CHREB when the research is complete or terminated.

Approval by the REB does not necessarily constitute authorization to initiate the conduct of this research. The Principal Investigator is responsible for ensuring required approvals from other involved organizations (e.g., Alberta Health Services, community organizations, school boards) are obtained.

Approved By: Date:

Stacey A. Page, PhD, Chair, CHREB January 2, 2019

Note: This correspondence includes an electronic signature (validation and approval via an online system).