



Conjoint Health Research Ethics Board
Research Services Office
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CERTIFICATION OF INSTITUTIONAL ETHICS APPROVAL

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

Ethics ID: REB16-1588_MOD3

Principal Investigator: Andrew Wallace Kirkpatrick

Co-Investigator(s): Chad Ball
Elijah Dixon
Christopher James Doig
Craig Jenne
Paul Kubes
Anthony Roderick MacLean
Paul McBeth

Student Co-Investigator(s): Derek Roberts

Study Title: Closed versus Open Abdomen in the Surgical Treatment of Severe Secondary Peritonitis: A Randomized Controlled Clinical Trial

Sponsor:

Effective: 12 May 2018

Expires: 12 May 2019

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.

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.

This modification has been reviewed by the full Conjoint Health Research Ethics Board of the University of Calgary on August 16, 2018.

An alteration to the consent requirement has been granted according to the Tri-Council Policy Statement, Article 3.7A.

The following documents have been approved:

- V4.7 - Informed Patient Consent-form_early regained capacity_clean version_Sept 2018.docx
- V4.7 - Deferred Surrogate and Regained Capacity Consent Form_Clean_Sept 2018.docx

Approved By:

Kathleen Oberle, PhD, Vice-Chair , CHREB

Date:

05 September 2018

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