



Conjoint Health Research Ethics Board
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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: REB16-1588

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 (if applicable):

Effective: May 12, 2017

Expires: May 12, 2018

This study has been reviewed by the full Conjoint Health Research Ethics Board of the University of Calgary on April 20, 2017.

The following documents have been approved for use:

- Informed Consent-form_ver3_May 2017-clean, 3, May 11, 2017
- Case report Form-the COOL study, 1.0, March 15, 2017
- V2.0 Protocol_close or open abdomen RCT for IAS-ver2-201703, 2.0, March 15, 2017

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.

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:

Kathleen Oberle, PhD, Vice-Chair , CHREB

Date:

May 12, 2017

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