Provincial Research Administration
Administrative Approval for Research to Proceed
June 19, 2017

Study Information			
Title: Closed versus Open Abdomen in the Surgical Treatment of Severe Secondary Peritonitis: A Randomized Controlled Clinical Trial		**Expected End Date:**	November 1, 2021
		Expected No. of Subjects:	300
		Study Type	Observational
		Intervention Type (if applicable):	Choose an item.
Research Ethics Board			
REB #:	REB16-1588	**REB Approval Date:**	12 May 2017
Research Finance			
Funding Source (If multiple sources, select all that apply)	None Choose an item. If other (specify):	**Sponsor/Funder Name(s)**	Unfunded

Principal Investigator:		Primary Contact:	
Supervisor for Trainee/ Project ☐		**Student/Trainee Level:**	Choose an item.
Name:	Andrew Wallace Kirkpatrick	**Name:**	(Jimmy) Zhengwen Xiao
Faculty:	Cummings School of Medicine	**Title:**	Study Coordinator
Department:	Surgery	**Research Team/Unit:**	
Division/Section:	General Surgery	**Phone:**	403-944-8750
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A. Study Summary

This study is a prospective randomized clinical study to examine the surgical treatment of severe complicated intra-abdominal sepsis patients (SCIAS). SCIAS patients can receive either a closed of open laparotomy as part of standard of care treatment. The study will comprise the randomized decision to either A) primarily close the fascia after laparotomy (CLOSED); or B) leave the fascia open after laparotomy and apply a temporary abdominal closure (TAC) device (OPEN). Although debatable, both procedures (CLOSED or OPEN abdomen) are acceptable based on current suggested standard of care. Thus, high quality data to direct clinical decision making in this highly lethal condition is urgently required.

B. Population under Recruitment (lay language):

Patients at Foothills Medical Centre with severe complicated abdominal sepsis requiring laparotomy for source control.

C. Operational Impacts:

Patients will be recruited by the attending surgeon just prior to their sepsis surgeries. These patients will be urgently taken to the operating room under the care of the surgical attending who will be present for the operation. The surgeries performed are standard of care, but patients that are determined to be eligible for the study in the operating room during their procedure will be randomized either to the Open Abdomen surgery or the Closed Abdomen surgery. Recovering patients will be in the Adult ICU, Unit 102 or Unit 44. Here they will be consented once conscious, and members of the research team will take samples of blood and peritoneal fluid taken at 7 time points over the first 72 hours after surgery. These samples are research samples and will be analyzed in UC labs, not AHS.

Operational Areas Impacted /Approvers

Unit/ Program	Facility	City/Town	Approver Name	Title	Approval Date

Surgery, Operating Room	Foothills Medical Centre	Calgary	Holly Mackin, Assessor: Myrna Trotchie	Executive Director: Surgery, Trauma Services & SAOTPD	June 19, 2017
Trauma Services (Unit 44)	Foothills Medical Centre	Calgary	Holly Mackin, Assessor: Chris Vis	Executive Director: Surgery, Trauma Services & SAOTPD	June 19, 2017
General Surgery, Inpatient Unit 102	Foothills Medical Centre	Calgary	Holly Mackin, Assessor: Sonia Ficaccio-Scarcelli	Executive Director: Surgery, Trauma Services & SAOTPD	June 19, 2017
Intensive Care Unit, Adult	Foothills Medical Centre	Calgary	Caroline Hatcher, Assessor: Kelly Coutts	Executive Director: FMC	June 19, 2017

D. Data/System Impacts:

The PI and study coordinator will use SCM and eCritical Metavision to obtain information related to participants' sepsis surgery and recovery. These patients are being monitored for 72 hours following surgery while they are in the ICU. Both the PI and the coordinator have current access to both of these systems. The PI has both clinical and research is encouraged to use research access while performing research related activities.

Paper charts from Health Records at FMC may also be needed to obtain patient information.

Since the study is using delayed consent for participants, Netcare cannot be used by study team members to obtain patient information for the purposes of the research study.

HIA/FOIP Research Agreement Status: Completed
If applicable, enter date fully executed: 5/26/2017
If HIA/FOIPP Research Agreement is required and in progress at the time Administrative Approval is granted, the fully executed agreement will be required for the release of the data product.

Repository(s) Impacted / Signatories

Database/System/Repository Name	Assigned Analyst	Repository Owner Name	Title
Sunrise Clinical Manager	Direct Access	Brenda Huband	VP & Chief Health Operations Officer (Southern AB)
eCritical MetaVision	Direct Access	Brenda Huband	VP & Chief Health Operations Officer (Southern AB)
Health Information Management – Calgary Zone	N/A	Diane Talbot	Manager, Health Information Records Management, Calgary Zone

AHS Administrative Approval (All Zones Except Edmonton):

Date Issued	Name of Approver	Title	Approved
June 19, 2017	Cheryl J Vos	Research Administration Advisor