CHEO Research Ethics Board
Approval - Full Board Review

Principal Investigator: Dr. Kusum Menon
REB Protocol No: 14/05E
Romeo File No: 20140074
Project Title: CHEOREB# 14/05E - Steroids in Fluid and/or Vasoactive Infusion Dependent Pediatric Shock (STRIPES) – Pilot Study
Primary Affiliation: Clinical Research\Pediatric Intensive Care
Protocol Status: Active
Approval Date: May 08, 2014
Valid Until: April 15, 2015
Annual Renewal Submission Deadline: March 15, 2015

Documents Reviewed & Approved:

Document Name	Comments	Version Date
Product Monograph	Solu-Cortef Act-O-Vials 9Hydrocortisone sodium succinate for injection USP)	2013/04/05
Protocol	Protocol_STRIPES_Version#1, Date: 5/May/2014_clean version	2014/05/05
Consent Form	Consent Form_STRIPES_Version#1, Date: 5/May/2014_clean version	2014/05/05
Recruitment Poster	Information Poster_STRIPES_Version#1, Date: 5/May/2014_clean version	2014/05/05
Other Document	Deferred Consent Pamphlet_STRIPES_Version#1, Date:	2014/05/05

	5/May/2014_clean version	
Recruitment Poster	Bedside Poster_STRIPES_Date: 5/May/2014 (new document)	2014/05/05
Other Document	Flowchart: STRIPES Study Consent Process_Version#1, Date: 5/May/2014 (new document)	2014/05/05
Other Document	Email Correspondence with Health Canada regarding CTA for STRIPES Study_5/May/2014	2014/05/05

This protocol was approved at a meeting of the CHEO Research Ethics Board in which the quorum rules were met and only those REB members who were independent of the investigator(s) conducting the study voted on the final decision**.**

In fulfilling its mandate, the CHEO REB is guided by: Tri-Council Policy Statement; ICH Good Clinical Practice Practices: Consolidated Guideline; Applicable laws and regulations of Ontario and Canada (e.g., Health Canada Division 5 of the Food and Drug Regulations & the Food and Drugs Act - Medical Devices Regulations).

Final approval is granted with the understanding that the investigator agrees to comply with the following requirements:

1. The investigator must conduct the study in compliance with the protocol and any additional conditions set out by the Board.
2. The investigator must not implement any deviation from, or changes to, the protocol without the approval of the REB except where necessary to eliminate an immediate hazard to the research subject, or when the change involves only logistical or administrative aspects of the study (e.g., change of telephone number or research staff). As soon as possible, however, the protocol deviation form and, if appropriate, the proposed protocol amendment(s) should be submitted to the Board for review.
3. The investigator must, prior to use, submit to the Board changes to the study documentation, e.g., changes to the informed consent letters, recruitment materials. Should major revisions to the consent form be made, the investigator agrees to re-consent those subjects who have originally consented to the study and who wish to continue on the study.
4. For clinical drug or device trials, investigators must promptly report to the REB all adverse events that are both serious and unexpected (SAEs). For SAE reports on CHEO patients, the investigator must also comply with the hospital-wide Policy regarding, Procedures For Considering Medical Error In The Differential Diagnosis of Severe Adverse Events (SAE) Associated with the Drugs Administered in a Clinical Trial (see http://cheonet/data/1/rec_docs/3792_Medical%20Error%20Policy%20revised%20january%202 0061.doc).

5. For all other research studies, investigators must promptly report to the REB all unexpected and untoward occurrences (including the loss or theft of study data and other such privacy breaches).
6. Investigators must promptly report to the REB any new information regarding the safety of research subjects (e.g., changes to the product monograph or investigator's brochure for drug trials). Where available, any reports produced by Data Safety Monitoring Board should be submitted to the REB.
7. Investigators must notify the REB of any study closures (temporary, premature or permanent), in writing along with an explanation of the rationale for such action.
8. Investigators must submit an annual renewal report to the REB 30 days prior to the expiration date stated above.
9. Investigators must submit a final report at the conclusion of the study.
10. Investigators must provide the Board with French versions of the consent form, unless a waiver has been granted.

For complete procedures relating to these modifications, please refer to the REB website at http://www.cheori.org/en/research ethicsboard or contact Sharon Haig, Ethics Coordinator at shaig@cheo.on.ca or 613-737-7600 ext. 2128.

Regards,

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