

ROC Site Status & Enrollment as of 4/4/2007

Ottawa	REB	Initial REB Approval	REB Approval for Final Protocol	FDA Amendment Approval	Shock Cohort Enrolled	TBI Cohort Enrolled	Community Consultation Completed
Overarching REB-Ottawa Hospital					22	19	See below*
Hospitals							
Halton							
Joseph Brant Memorial	Joseph Brant	6/22/2006	6/22/2006	1/25/2007			
Kingston							
Hotel Dieu Hospital	Queens University	4/5/2006	5/31/2006	pending			
Kingston General Hospital	Queens University	5/31/2006	5/31/2006	pending			
Cambridge							
Cambridge Memorial Hospital	Tri-Hospital	11/2/2005	5/10/2006	12/6/2006			
Grand River Hospital Corporation	Tri-Hospital	11/2/2005	5/10/2006	12/6/2006			
St. Mary's General Hospital	Tri-Hospital	11/2/2005	5/10/2006	12/6/2006			
Cornwall							
Cornwall Community Hospital	Cornwall						
London							
London Health Science Centre	U Western Ontario	5/23/2006	5/23/2006	2/6/2007			
The Children's Hospital of Western Ontario	U Western Ontario	5/23/2006	5/23/2006	2/6/2007			
Niagara							
Niagara Health System-Greater Niagara	Niagara Health	8/15/2006	8/15/2006	2/28/2007			
Niagara Health System-Douglas Memorial	Niagara Health	8/15/2006	8/15/2006	2/28/2007			
Niagara Health System-Port Colborne	Niagara Health	8/15/2006	8/15/2006	2/28/2007			
Niagara Health System-St. Catharines	Niagara Health	8/15/2006	8/15/2006	2/28/2007			
Niagara Health System-Welland	Niagara Health	8/15/2006	8/15/2006	2/28/2007			
Ottawa							
Children's Hospital of Eastern Ontario (CHEO)	CHEO	6/14/2006	6/14/2006	12/6/2006			
Ottawa Hospital-Civic Campus	Ottawa Hospital	8/30/2005	3/3/2006	11/22/2006			
Ottawa Hospital-General Campus	Ottawa Hospital	8/30/2005	3/3/2006	11/22/2006			
Thunder Bay							
Thunder Bay Regional Hospital-McKellar	Thunder Bay	12/20/2005	8/18/2006	1/8/2007			
Thunder Bay Regional Hospital-Port Arthur	Thunder Bay	12/20/2005	8/18/2006	1/8/2007			
Sudbury							
Sudbury Regional Hospital-St. Joseph's	Sudbury Regional	6/15/2006	6/15/2006	1/8/2007			
Windsor							
Hotel Dieu Grace Hospital	Hotel-Dieu Grace	8/3/2005	5/23/2006	11/28/2006			
EMS Agencies							
Halton							
Halton Region Ambulance Service##	Joseph Brant	6/22/2006	6/22/2006	1/25/2007			
Kingston							

Frontenac Paramedic Service##	Queens University	5/31/2006	5/31/2006	pending				
Cambridge								
Region of Waterloo EMS##	Tri-Hospital	11/2/2005	5/10/2006	12/6/2006				
Cornwall								
Prescott-Russell##	Ottawa Hospital	8/30/2005	3/3/2006	11/22/2006				
Cornwall SD & G##	Ottawa Hospital	8/30/2005	3/3/2006	11/22/2006				
London								
Thames EMS#	U Western Ontario	5/23/2006	5/23/2006	2/6/2007				
Niagara								
Niagara Region EMS#	Niagara Health	8/15/2006	8/15/2006	2/27/2007				
Ottawa								
Ottawa Paramedic Service-Rural#	Ottawa Hospital	8/30/2005	3/3/2006	11/22/2006				
Ottawa Paramedic Service-Urban#	Ottawa Hospital	8/30/2005	3/3/2006	11/22/2006				
Sudbury								
Greater Sudbury EMS-Rural#	Sudbury Regional	6/15/2006	6/15/2006	1/8/2007				
Greater Sudbury EMS-Urban#	Sudbury Regional	6/15/2006	6/15/2006	1/8/2007				
Thunder Bay								
Superior North EMS#	Thunder Bay	12/20/2005	6/19/2006	1/8/2007				
Windsor								
Essex Windsor EMS#	Hotel-Dieu Grace	8/3/2005	5/23/2006	11/28/2006				
Essex Windsor-AA & M#	Hotel-Dieu Grace	8/3/2005	5/23/2006	11/28/2006				
Essex Windsor-Harrow#	Hotel-Dieu Grace	8/3/2005	5/23/2006	11/28/2006				
Essex Windsor-Sun Parlour#	Hotel-Dieu Grace	8/3/2005	5/23/2006	11/28/2006				
*Canadian sites adhere to the Tri-Council Agreement & Research Ethics Board (equivalent to US IRB) requirements for Canada								
Canadian requirements allow community consultation to be delegated to the REB								
#Enrolling subjects								
##Not enrolling due to retraining EMS								

TBI Enrollment Breakdown as of 4/30/2007	HAL	KIN	KIN	CAM	CAM	CAM	COR	LON	LON	NIA	NIA	NIA	NIA	NIA	OTT	OTT	OTT	THU	THU	SUD	WIN	WIN		
EMS Agencies/Hospitals	Joseph Brant Mem	Hotel Dieu Hosp	Kingston General Hosp	Cambridge Mem Hosp	Grand River Hosp Corp	St. Mary's Gen Hosp	Cornwall Comm Hosp	London Hlth Sci Centre	The Children's Hosp/ Ont	Gtr Niagara Mem	Douglas Port Colborne	St Catharines Welland	Children's Hosp/ Ont	Ottawa Hosp-Civic	Ottawa Hosp-Gen	Thunder Bay Hosp-McKellar	Thunder Bay Hosp-Port Arthur	Sudbury Hosp-St. Joseph's Hosp	Hotel Dieu Grace Hosp	Non-ROC	Total			
Halton Region Ambulance Service	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Kingston Frontenac Paramedic Service	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Cambridge Region of Waterloo EMS	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	
Cornwall Prescott-Russell Cornwall SD & G	0	0	0	1	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	
London Thames EMS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4
Niagara Region EMS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Ottawa Paramedic Service-Rural	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Ottawa Paramedic Service-Urban	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Sudbury Greater Sudbury EMS-Rural	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Greater Sudbury EMS-Urban	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3
Thunder Bay Superior North EMS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Essex Windsor EMS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Essex Windsor-AA & M	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	0	4
Essex Windsor-Harrow	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Essex Windsor-Sun ParLOUR	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	2
Total for Hospital	0	0	2	1	3	0	0	4	0	0	0	0	0	0	3	0	0	0	0	0	6	0	19	



JOSEPH BRANT
MEMORIAL HOSPITAL

1230 North Shore Blvd.
Burlington, Ontario L7R 4C4
Tel: (905) 632-3730

January 27, 2007

Dr. Matt Stempien
Emergency Medicine
JBMH

Dear Dr. Stempien:

Re: Hypertonic Saline Trial – Resuscitation Outcomes Consortium (ROC)

At its meeting on January 25, 2007, the Ethics Committee reviewed and approved the amendments to the Research Protocol.

Please advise the Ethics Committee if there are changes to the approved study documents.

Sincerely,

Elizabeth Wensley
Director - Organizational Development &
Quality Improvement
Member - Ethics Committee

/dm



JOSEPH BRANT
MEMORIAL HOSPITAL

1230 North Shore Blvd.
Burlington, Ontario L7R 4C4
Tel: (905) 632-3730

June 26, 2006

Dr. M. Stempien / Ann Wilson / David Campbell
Base Hospital Program for Halton Region

Dear Dr. Stempien, Ann & David:

Re: Hypertonic Saline Trial -Resuscitation Outcomes Consortium (ROC)

At its meeting on June 22, 2006, the Ethics Committee received and approved the Application for Approval of Research Protocol and supporting documentation for the above noted study.

Please advise the Ethics Committee if there are changes to the approved study documents.

Sincerely,

Elizabeth Wensley
Director - Organizational Development &
Quality Improvement
Member - Ethics Committee

/dm



OFFICE OF RESEARCH SERVICES

Fleming Hall, Jemmett Wing
Queen's University
Kingston, Ontario, Canada K7L 3N6
Tel 613 533-6081
Fax 613 533-6806
ors@post.queensu.ca
www.queensu.ca/vpr/

May 31, 2006

Dr. Andrew Reed
Medical Director
Regional Base Hospital for Southeastern Ontario
Hotel Dieu Hospital

Re: "Resuscitation Outcomes Consortium Hypertonic Saline Study Protocol"
EMED-076-06

Dear Dr. Reed,

I am writing to acknowledge receipt of the following:

- Your letter dated April 27, 2006 which provided notification of amendments to the protocol for the above-named study
- Your letter dated May 12, 2006 which requested approval for some changes to the Information Sheet

I have reviewed the protocol modifications (March 20, 2006) and the revised information sheet and hereby give my approval. These amendments will be reported to the Research Ethics Board.

Yours sincerely,

A handwritten signature in cursive script that reads "Albert Clark".

Albert Clark, Ph.D.
Chair
Research Ethics Board

AFC/kr

think Research
think Queen's

QUEEN'S UNIVERSITY HEALTH SCIENCES & AFFILIATED TEACHING
HOSPITALS RESEARCH ETHICS BOARD



Queen's University, in accordance with the "Tri-Council Policy Statement, 1998" prepared by the Medical Research Council, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada requires that research projects involving human subjects be reviewed annually to determine their acceptability on ethical grounds.

A Research Ethics Board composed of:

Dr. A.F. Clark	Emeritus Professor, Department of Biochemistry, Faculty of Health Sciences, Queen's University (Chair)
Dr. S. Burke	Emeritus Professor, School of Nursing, Queen's University
Rev. T. Deline	Community Member
Dr. M. Evans	Community Member
Dr. M. Green	Assistant Professor, Department of Family Medicine, Queen's University
Ms. I.C. Knott	Research & Evaluation, Southeastern Regional Geriatric Program, Providence Continuing Care Centre – St. Mary's of the Lake Hospital Site
Dr. J. Low	Emeritus Professor, Department of Obstetrics and Gynaecology, Queen's University and Kingston General Hospital
Dr. H. Murray	Assistant Professor, Department of Emergency Medicine, Queen's University
Dr. W. Racz	Emeritus Professor, Department of Pharmacology & Toxicology, Queen's
Dr. H. Richardson	Assistant Professor, Department of Community Health & Epidemiology Project Coordinator, NCIC CTG, Queen's University
Dr. B. Simchison	Assistant Professor, Department of Anesthesiology, Queen's University
Dr. A.N. Singh	WHO Professor in Psychosomatic Medicine and Psychopharmacology Professor of Psychiatry and Pharmacology Chair and Head, Division of Psychopharmacology, Queen's University
Dr. S. Taylor	Director, Office of Bioethics, Queen's University and Kingston General Hospital; Associate Professor, Department of Medicine, Queen's University
Ms. K. Weisbaum	LL.B. and Adjunct Instructor, Department of Family Medicine (Bioethics)

has examined the protocol, telephone script, interview questions for GOSE and DRS, advertisement and information sheet for the project entitled "Hypertonic Resuscitation Following Traumatic Injury" as proposed by Dr Andrew Reed of the Department of Emergency Medicine at Queen's University and considers it to be ethically acceptable. This approval is valid for one year. If there are any amendments or changes to the protocol affecting the subjects in this study, it is the responsibility of the principal investigator to notify the Research Ethics Board. Any unexpected serious adverse event occurring locally must be reported within 2 working days or earlier if required by the study sponsor. All other serious adverse events must be reported within 15 days after becoming aware of the information."

Albert Clark

Chair, Research Ethics Board

April 5, 2006
Date

ORIGINAL TO INVESTIGATOR - COPY TO DEPARTMENT HEAD - COPY TO HOSPITAL(S) - P&I - FILE COPY

EMED-076-06

2006-02-13



Address correspondence to:
 M. Coughlin, Ph.D.
 Chair, Tri-Hospital Research Ethics Board
 Grand River Hospital
 P.O. Box 9056
 3570 King St.E.
 Kitchener, ON. N2G 1G3
 Tel (519) 749-4300 ext. 7348
 Fax (519) 894-8329
 coughlin@mcmaster.ca

December 13, 2006

Dr. David Waldbillig, Site Investigator
 c/o Kieran Ballah
 Waterloo Region-Wellington-Dufferin Base Hospital
 Paramedic Program
 240 Holiday Inn Drive, Suite 0
 Cambridge, ON N3C 3X4

Dear Dr. Waldbillig:

RE: THREB #58(3)05 – Letter of Approval for Amendment IND 12505 and 12506 dated November 22, 2006 for Research Study – “Hypertonic Resuscitation Following Traumatic Injury” – Dr. Ian Stiell, The Ottawa Hospital - Principal Investigator

Study Identification Number:	THREB#58(3)05
Study Approval Date:	May 10, 2006
Approval Date for Amendments IND 12505 and 12506:	December 6, 2006
Study Expiry Date:	May 9, 2007

Thank you for your letter of November 15, 2006 requesting approval of amendments IND 12505 and 12506 for the above study.

The Tri-Hospital Research Ethics Board (THREB) has reviewed Amendments IND 12505 and 12506 at the December 6, 2006 meeting for the above study and they are considered acceptable. This will certify a quorum was present and approval is granted.

NOTE: The Study Identification Number “THREB ID#58(3)05” has been assigned to your project. Please use this number on all future correspondence.

Please call me if you have any questions.

Sincerely,

Michael D. Coughlin, Ph.D.
 Chair, Tri-Hospital Research Ethics Board

May.18. 2006 1:31PM CAMBRIDGE MEM BASE HOSPITAL

No.0390 P. 2/5



Address correspondence to:

M. Coughlin, Ph.D.
 Chair, Tri-Hospital Research Ethics Board
 Grand River Hospital
 P.O. Box 9056
 3570 King St.E.
 Kitchener, ON. N2G 1G3
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 Fax (519) 894-8329
 coughlin@mcmaster.ca

May 10, 2006

Dr. David Waldbillig, Site Investigator
 c/o Kieran Ballah
 Waterloo Region-Wellington-Dufferin Base Hospital
 Paramedic Program
 240 Holiday Inn Drive, Suite 0
 Cambridge, ON N3C 3X4

Dear Dr. Waldbillig:

RE: THREB #58(3)05 – Letter of Approval for Research Study – “Hypertonic Resuscitation Following Traumatic Injury” – Dr. Ian Stiell, The Ottawa Hospital - Principal Investigator

Study Identification Number:	THREB#58(3)05
Study Approval Date:	May 10, 2006
Study Expiry Date:	May 9, 2007

Thank you for the recommended revisions requested by Tri-Hospital Research Ethics Board (THREB) at the November 2, 2005 meeting for the above study.

The research application dated September 9, 2005; Protocol, revised Information Sheet with your date of October 21, 2005, Version 3 and as received by us May 9, 2006, and the Phone Interview Consent Form for the above study has been reviewed by the Tri-Hospital Research Ethics Board (THREB), and considered acceptable. This will certify a quorum was present and approval is granted. This study will be reviewed in one year's time.

Please find enclosed an original signed "Certificate of Approval to Conduct Proposed Study" at Cambridge Memorial Hospital, Grand River Hospital, and St. Mary's General Hospital for one year.

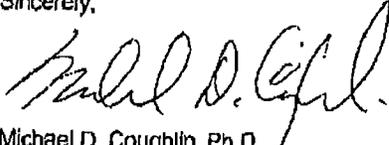
Also, attached is a "Declaration of Conflict of Interests for Research Studies" form, sign and return to me for our files.

• Page 2

NOTE: The Study Identification Number "THREB ID#58(3)05" has been assigned to your project
Please use this number on all future correspondence.

Please call me if you have any questions.

Sincerely,



Michael D. Coughlin, Ph.D.
Chair, Tri Hospital Research Ethics Board

Encl.



**TRI-HOSPITAL RESEARCH ETHICS BOARD (THREB)
CERTIFICATE OF APPROVAL TO CONDUCT PROPOSED STUDY**

P.O. Box 9056, Kitchener, Ontario, N2G 1G3
Tel: (519) 749-4300 ext. 7187 Fax: (519) 894-8329

Tri-Hospital Research Ethics Board Membership

Michael Coughlin, PhD
Chair, Tri-Hospital Research Ethics Board

Stewart Boecker, MHA
Vice President/Chief Financial Officer

Carolyn Campbell, MD
Oncologist

Edmond Cheumard, MD
Oncologist

Shaun Devine, LL.B
Community Member

Nancy Martin, PhD
Director, Research & Performance Metrics

Paul Motz, B.Sc
Community Member

Bea Mudge, RN, MBA, CHE
Vice President, Patient Services & Chief Nursing Officer

Don Shilton, MBA
Program Manager
Cardiac Services

Erin Tjam, PhD
Director of Research

Noela Vorsteveld, B.Sc Pharm.
Manager, Pharmacy

This Tri-Hospital Research Ethics Board operates in compliance with the ICH Good Clinical Practice Guidelines and the Tri-Council Policy Statement. Ethical Conduct for Research Involving Humans.

The application for research study titled "Hypertonic Resuscitation Following Traumatic Injury" with Principal Investigator as Dr. Ian Stiell, The Ottawa Hospital and Site Investigator as Dr. David Waldbillig was reviewed at the THREB meeting of November 2, 2005 and is considered acceptable by the Tri-Hospital Research Ethics Board of Cambridge Memorial Hospital and Grand River Hospital and St. Mary's General Hospital. **This approval is valid for one year.**

Approval is granted to conduct the research project in accordance with the protocol specified in the application.

Requirements for ongoing approval:

- a) Annual review of the submission will be undertaken by the THREB.
- b) All significant adverse events experienced by subjects enrolled in the trial must be reported to the THREB as outlined in the letter to the investigator.
- c) Any changes in the protocol, information sheets, questionnaires, or informed consent documents must be reported to the Chair, THREB immediately.
- d) Upon completion of the study, the THREB must be notified in writing, given a short summary of the progress of the trial (i.e. number of patients enrolled, problems encountered, etc.) and a full report of study results.
- e) The final report on the study is to be provided to the THREB within three months of study completion.

Michael Coughlin, Ph.D.
Chair, Tri-Hospital Research Ethics Board
c/o Research & Performance Metrics
Grand River Hospital Corporation

May 9, 2007

Expiry Date



Cornwall Community Hospital
Hôpital communautaire de Cornwall

www.cornwallhospital.ca
www.hopitalcornwall.ca

March 22, 2007

Dr. Justin Maloney
Medical Director
Ottawa Base Hospital
The Ottawa Hospital-General Campus
501 Smyth Rd
Ottawa, Ontario K1H 8L6

Dear Dr. Maloney

Re: Protocol Hypertonic Resuscitation following Traumatic Injury Study

I hereby wish to confirm that at its regular meeting of December 4, 2006, the Ethics Committee of Cornwall Community Hospital reviewed and approved the amendments as listed in the summary letter received from Dr. Geoff Heseltine November 15, 2006.

At its regular meeting of December 13, 2006, the Patient Care Medical Staff Committee reviewed and approved the amendments.

Should you have any questions, please do not hesitate to contact me.

Sincerely,

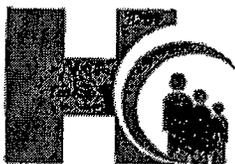
Christine Penney, RN, MSc
Director Quality Performance

c.c. Jane Bennett, Research Assistant, Ottawa Hospital Research Institute
Dr. Geoff Heseltine, Cornwall Community Hospital ED Physician

CP/cng

840 avenue McConnell Avenue
Cornwall, Ontario K6H 5S5
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Fax / Téléc.: (613) 930-4502

510 rue Second Street E.
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Cornwall Community Hospital
Hôpital communautaire de Cornwall

www.cornwallhospital.ca
www.hopitalcornwall.ca

February 28, 2006

Dr. Luc Brière and Ms. Cindy Brandt
Associate Base Hospital Program
Eastern Counties
510 Second Street East
Cornwall, Ontario
K6H 1Z6

Dear Dr. Brière and Ms. Brandt

Re: Resuscitation Outcomes Consortium (ROC) Study

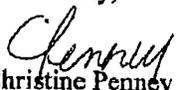
I hereby wish to confirm that, at its regular meeting of February 2, 2006, the Ethics Committee of Cornwall Community Hospital approved participation in the "Resuscitation Outcomes Consortium (ROC) Study".

As part of its review, the Committee received the following documents:

- Letter dated November 2, 2005 from the Associate Base Hospital Program, Eastern Counties;
- Research/Trial/Registry Application Form dated October 28, 2005;
- RescueFlow® (Hypertonic Saline Dextran, HSD) Investigator's Brochure, Edition Number: 02, Release Date: 2004, June 30;
Information Sheet – Hypertonic Resuscitation Following Traumatic Injury;
Draft HS Budget, Version 3, printed on 11/1/2005;
ROC Hypertonic Saline Trial – Title: Hypertonic Resuscitation following Traumatic Injury and appendices;
Letter dated May 27, 2005 from Health Canada;
Letter dated August 30, 2005 from The Ottawa Hospital Research Ethics Board;
Letter dated December 23, 2005 from Associate Base Hospital Program, Eastern Counties; and
Protocol Modification Summary "Hypertonic Resuscitation Following Traumatic Injury", September 9, 2005.

Should you have any questions, please do not hesitate to contact me.

Yours truly,


Christine Penney
Director
Quality Performance

mm

840 avenue McConnell Avenue
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Office of Research Ethics

The University of Western Ontario
Room 00046 Dental Sciences Building, London, ON, Canada N6A 5C1
Telephone: (519) 661-3036 Fax: (519) 850-2466 Email: ethics@uwo.ca
Website: www.uwo.ca/research/ethics

Use of Human Subjects - Ethics Approval Notice

Principal Investigator: Dr. J. Dreyer

Review Number: 12098

Review Date: February 6, 2007

Revision Number:

Protocol Title: Hypertonic Resuscitation Following Traumatic Injury

Department and Institution: Medicine, London Health Sciences Centre

Sponsor: NIH-NATIONAL INSTITUTE OF HEALTH

Ethics Approval Date: February 6, 2007

Expiry Date: June 30, 2008

Documents Reviewed and Approved: revised study methodology, addition of a co-investigator, revised inclusion/exclusion criteria

Documents Received for Information:

This is to notify you that The University of Western Ontario Research Ethics Board for Health Sciences Research involving Human Subjects (HSREB) which is organized and operates according to the Tri-Council Policy Statement and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted full board approval to the above named research study on the approval date noted above. The membership of this REB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

This approval shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to that time you must request it using the UWO Updated Approval Request Form.

During the course of the research, no deviations from, or changes to, the protocol or consent form may be initiated without prior written approval from the HSREB except when necessary to eliminate immediate hazards to the subject or when the change(s) involve only logistical or administrative aspects of the study (e.g. change of monitor, telephone number). Expedited review of minor change(s) in ongoing studies will be considered. Subjects must receive a copy of the signed information/consent documentation.

Investigators must promptly also report to the HSREB:

- a) changes increasing the risk to the participant(s) and/or affecting significantly the conduct of the study;
- b) all adverse and unexpected experiences or events that are both serious and unexpected;
- c) new information that may adversely affect the safety of the subjects or the conduct of the study.

If these changes/adverse events require a change to the information/consent documentation, and/or recruitment advertisement, the newly revised information/consent documentation, and/or advertisement, must be submitted to this office for approval.

Members of the HSREB who are named as investigators in research studies, or declare a conflict of interest, do not participate in discussion related to, nor vote on, such studies when they are presented to the HSREB.

Chair of HSREB: Dr. John W. McDonald
Deputy Chair: Susan Hoddinott

Ethics Officer to Contact for Further Information

Janice Sutherland (jsutherl@uwo.ca)

Jennifer McEwen (mcewen4@uwo.ca)

Denise Grafton (dgrafton@uwo.ca)

This is an official document. Please retain the original in your files.

cc: ORE File
LHRI



Office of Research Ethics

The University of Western Ontario
Room 00045 Dental Sciences Building, London, ON, Canada N6A 5C1
Telephone: (519) 861-3036 Fax: (519) 850-2466 Email: ethics@uwo.ca
Website: www.uwo.ca/research/ethics

Use of Human Subjects - Ethics Approval Notice

Principal Investigator: Dr. J. Dreyer

Review Number: 12097

Review Date: February 6, 2007

Revision Number:

Protocol Title: Hypertonic Resuscitation Following Traumatic Injury for Hypovolemic Shock Patients.

Department and Institution: Medicine, London Health Sciences Centre

Sponsor: NIH-NATIONAL INSTITUTE OF HEALTH

Ethics Approval Date: February 6, 2007

Expiry Date: June 30, 2008

Documents Reviewed and Approved: revised study methodology; addition of a co-investigator, revised inclusion/exclusion criteria

Documents Received for Information:

This is to notify you that The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB) which is organized and operates according to the Tri-Council Policy Statement and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted full board approval to the above named research study on the approval date noted above. The membership of this REB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

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- b) all adverse and unexpected experiences or events that are both serious and unexpected;
- c) new information that may adversely affect the safety of the subjects or the conduct of the study.

If these changes/adverse events require a change to the information/consent documentation, and/or recruitment advertisement, the newly revised information/consent documentation, and/or advertisement, must be submitted to this office for approval.

Members of the HSREB who are named as investigators in research studies, or declare a conflict of interest, do not participate in discussion related to, nor vote on, such studies when they are presented to the HSREB.

Chair of HSREB: Dr. John W. McDonald

Deputy Chair: Susan Hodinot

Ethics Officer to Contact for Further Information

- Janice Sultherland (jsulther@uwo.ca)
- Jennifer McEwen (jmcewen4@uwo.ca)
- Denise Grafton (dgrafton@uwo.ca)

This is an official document. Please retain the original in your files.

cc: ORE File
LHRI



Office of Research Ethics

The University of Western Ontario
Room 00045 Dental Sciences Building, London, ON, Canada N6A 5C1
Telephone: (519) 661-3036 Fax: (519) 850-2466 Email: ethics@uwo.ca
Website: www.uwo.ca/research/ethics

Use of Human Subjects - Ethics Approval Notice

Principal Investigator: Dr. J. Dreyer

Review Number: 12098

Revision Number:

Protocol Title: Hypertonic Resuscitation Following Traumatic Injury

Department and Institution: Medicine, London Health Sciences Centre

Sponsor: NIH-NATIONAL INSTITUTE OF HEALTH

Ethics Approval Date: May 23, 2006

Expiry Date: June 30, 2008

Documents Reviewed and Approved: UWO Protocol, HTS TBI Letter of Information and Consent dated April 28, 2006

Documents Received for Information:

This is to notify you that The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB) which is organized and operates according to the Tri-Council Policy Statement and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted full board approval to the above named research study on the approval date noted above. The membership of this REB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

This approval shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to time you must request it using the UWO Updated Approval Request Form.

During the course of the research, no deviations from, or changes to, the protocol or consent form may be initiated without prior written approval from the HSREB except when necessary to eliminate immediate hazards to the subject or when the change(s) involve only logistical or administrative aspects of the study (e.g. change of monitor, telephone number). Expedited review of minor change(s) in ongoing studies will be considered. Subjects must receive a copy of the signed information/consent documentation.

Investigators must promptly also report to the HSREB:

- a) changes increasing the risk to the participant(s) and/or affecting significantly the conduct of the study;
b) all adverse and unexpected experiences or events that are both serious and unexpected;
c) new information that may adversely affect the safety of the subjects or the conduct of the study.

If these changes/adverse events require a change to the information/consent documentation, and/or recruitment advertisement, the newly revised information/consent documentation, and/or advertisement, must be submitted to this office for approval.

Members of the HSREB who are named as investigators in research studies, or declare a conflict of interest, do not participate in discussion related to, nor vote on, such studies when they are presented to the HSREB.

Handwritten signature of Jennifer McEwen

Chair of HSREB: Dr. John W. McDonald
Deputy Chair: Susan Hoddinott

Ethics Officer to Contact for Further Information

Table with 3 columns: [X] Janice Sutherland (jsuther@uwo.ca), [X] Jennifer McEwen (jmcewen4@uwo.ca), [] Ethics Officer (ethics@uwo.ca)

This is an official document. Please retain the original in your files.

cc: ORE File
LHRI
Faxed: Y/N



Office of Research Ethics

The University of Western Ontario
Room 00045 Dental Sciences Building, London, ON, Canada N6A 5C1
Telephone: (519) 661-3036 Fax: (519) 850-2466 Email: ethics@uwo.ca
Website: www.uwo.ca/research/ethics

Use of Human Subjects - Ethics Approval Notice

Principal Investigator: Dr. J. Dreyer

Review Number: 12097

Revision Number:

Protocol Title: Hypertonic Resuscitation Following Traumatic Injury for Hypovolemic Shock Patients.

Department and Institution: Medicine, London Health Sciences Centre

Sponsor: NIH-NATIONAL INSTITUTE OF HEALTH

Ethics Approval Date: May 23, 2006

Expiry Date: June 30, 2008

Documents Reviewed and Approved: UWO Protocol, HTS Shock Letter of Information and Consent dated April 28, 2006

Documents Received for Information:

This is to notify you that The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB) which is organized and operates according to the Tri-Council Policy Statement and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted full board approval to the above named research study on the approval date noted above. The membership of this REB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

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During the course of the research, no deviations from, or changes to, the protocol or consent form may be initiated without prior written approval from the HSREB except when necessary to eliminate immediate hazards to the subject or when the change(s) involve only logistical or administrative aspects of the study (e.g. change of monitor, telephone number). Expedited review of minor change(s) in ongoing studies will be considered. Subjects must receive a copy of the signed information/consent documentation.

Investigators must promptly also report to the HSREB:

- a) changes increasing the risk to the participant(s) and/or affecting significantly the conduct of the study;
- b) all adverse and unexpected experiences or events that are both serious and unexpected;
- c) new information that may adversely affect the safety of the subjects or the conduct of the study.

If these changes/adverse events require a change to the information/consent documentation, and/or recruitment advertisement, the newly revised information/consent documentation, and/or advertisement, must be submitted to this office for approval.

Members of the HSREB who are named as investigators in research studies, or declare a conflict of interest, do not participate in discussion related to, nor vote on, such studies when they are presented to the HSREB.

Chair of HSREB: Dr. John W. McDonald
Deputy Chair: Susan Hoddinott

Ethics Officer to Contact for Further Information

<input type="checkbox"/> Alice Sutherland (asutherland@uwo.ca)	<input checked="" type="checkbox"/> Jennifer McEwen (jmcewen4@uwo.ca)	<input type="checkbox"/> Ethics Officer (ethics@uwo.ca)
--	---	---

This is an official document. Please retain the original in your files.

cc: ORE File
LHSC
Faxed: Y/N



NIAGARA HEALTH SYSTEM
SYSTÈME DE SANTÉ DE NIAGARA
TOGETHER IN EXCELLENCE - LEADERS IN HEALTHCARE

Niagara Health System Research Ethics Board

65 Third Street, Welland, Ontario, Canada L3B 4W6
Tel: (905) 378-4647 Ext. 32202 Fax: (905) 732-2628

February 28, 2007

Dr. Douglas Munkley
Medical Director
Niagara Regional Base Hospital Paramedic Program
5546 Portage Road
Niagara Falls, Ontario
L2E 6X2

Dear Dr. Munkley:

Re: Resuscitation Outcome Consortium (ROC) Hypertonic Resuscitation Following Traumatic Injury Study

REB Assigned Number: 2005-12-002

On behalf of the Niagara Health System Research Ethics Board (REB) we would like to thank you for your letter dated February 21, 2007.

As stated in our letter dated January 26, 2007, this study had been conditionally approved until concerns were addressed as cited in our letter. By way of an expedited review meeting on February 27, 2007, we are now granting full (unconditional) approval for this study based on your responses to the concerns raised by the Board. An expedited summary will be reviewed at the next full Board meeting on March 22, 2007.

The Niagara Health System Research Ethics Board is in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human (TCPS), and the International Conference on Harmonization: Good Clinical Practice guidelines for IRBs, as well as, the Food and Drug Administration (FDA)/Therapeutic Products Directorate (TPD). As the Primary Investigator you are required to notify the REB of any amendments or changes in the protocol; significant protocol deviations, or termination of this project.

Should you require anything further, please do not hesitate to contact me through the REB office at 905-378-4647, ext 32202.

Sincerely,

Dr. K. Greenway, Chair
Research Ethics Board
Niagara Health System

/afc

Cc: Lorie Luinstra-Toohy

Research Ethics Board Membership

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Hospital Medicine

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Spiritual & Religious Care

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Research Methodology

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Privacy Law

George Groff
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Nursing

Rosamund Hennessey, RN
Research Methodology

Joanna Hill, BSc, MD
Physician

Nanci Howell, RN, BA, BScN
Research Methodology

Tracey MacDonald, RN, BScN, MHA, CHE
Vice President Patient Services and
Chief Nursing Executive
Senior Executive with Patient Service
Responsibilities

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Community

Janel Matthews, MScN, BScN, RN
Faculty of Nursing Brock University

Richard Raillon, MD, FRSC, FACS
Physician

Joe Seliska, R.Ph, BSc Phm
Pharmacy

John Yardley, PhD, MA, BSc
Research Methodology

Adrienne Clare
Administrative Assistant



Niagara Health System Research Ethics Board

65 Third Street, Welland, Ontario, Canada L3B 4W6
 Tel. (905) 378-4647 Ext. 32202 Fax: (905) 732-2628

August 16, 2006

Dr. Douglas Munkley
 Medical Director
 Niagara Regional Base Hospital Paramedic Program
 5546 Portage Road
 Niagara Falls, Ontario
 L2E 6X2

Dear Dr. Munkley:

Re: Resuscitation Outcome Consortium (ROC) Hypertonic Resuscitation Following Traumatic Injury Study

On behalf of the Niagara Health System Research Ethics Board (REB) we would like to thank you for your email dated June 23, 2006 for the above noted study.

By way of an expedited review meeting on August 15, 2006, we are now granting full (unconditional) approval to the above noted new application. This decision is based on the teleconference meeting held on June 22, 2006 whereby following conditions were agreed upon:

- 1 Issue of Opting Out for Citizens in the Region (an advertisement will be placed in the local newspapers which will explain the study being conducted and the bracelet-availability for opting out)
- 2 The advertisement will be posted in the three major papers every six months for the duration of the study. (Tracey Davey revised the draft advertisement and submitted these changes to John Wultchyn)
- 3 Monitoring and Education - further 1 hour sessions on education will be made mandatory for the advanced and primary care paramedics prior to the roll-out of this study
- 4 This study is considered high-risk and the parameters of the REB monitoring process need to be more intensive, an agreement was made to provide the REB with status reports every six months and an infrastructure to provide reporting locally.

An expedited summary will be reviewed at the full board meeting on August 24, 2006.

The Niagara Health System Research Ethics Board is in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human (TCPS), and the International Conference on Harmonization: Good Clinical Practice guidelines for IRB's, as well as, the Food and Drug Administration (FDA) Therapeutic Products Directorate (TPD). As the Primary Investigator you are required to notify the REB of any amendments or changes in the protocol; significant protocol deviations, or termination of this project.

Should you require anything further, please do not hesitate to contact me through the REB office at 905-378-4647, ext 32202.

Sincerely,

Dr. K. Greenway, Chair
 Research Ethics Board
 Niagara Health System

/afc

Cc: John Wultchyn ✓

Research Ethics Board Membership

Chair

Keith Greenway, BSc, MD, FRCPC
 Hospital Medicine

Vice Chairs

Tracey Davey, RN, BScN, CPHQ
 Regional Director, Quality, Education
 Research & Ethics

Nelson (Sandy) McKay, BA, LLB, QC
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 Faculty of Nursing Brock University

Richard Ralton, MD, FRSC, FACS
 Physician

Joe Sellske, R.Ph, BSc Pharm
 Pharmacy

John Yardley, PhD, MA, BSc
 Research Methodology

Adrienne Clare
 Administrative Assistant



Children's Hospital of Eastern Ontario
 Centre hospitalier pour enfants de l'est de l'Ontario

November 15, 2006

*Reed
15/11/06
Sting*

Dr. Carole Gentile,
 Chairman
 The Children's Hospital of Eastern Ontario Research Ethics Board
 The Children's Hospital of Eastern Ontario
 401 Smyth Road
 Ottawa, ON
 K1H 8L1

Dear Dr. Gentile,

Re: Protocol #06-09E Hypertonic Resuscitation following Traumatic Injury

The ROC investigators recently voluntarily suspended enrollment in this trial so that amendments could be made in order to better monitor these patients. A full protocol amendment document is attached. Issues amended include:

1. Notification of care providers regarding expected changes in serum sodium – An information sheet will be added to the EMS study kit, and will be delivered by the paramedic to the in-hospital care provider.
2. Monitoring of serum sodium – Sodiums will be monitored every eight hours for the first twenty-four hours on all patients in ICU. If the patient is being treated with Mannitol or 3% Saline, he will have his sodiums monitored every six hours for the duration of the intervention.
3. Central tracking of compliance with the new sodium monitoring system – The CTC will closely track the compliance with this plan, and deviations from the standard of care will be reviewed at regular intervals. If the DSMB finds that the standard of care is not in keeping with that required despite timely efforts at remediation, the site will be instructed to cease enrollment.
4. All sodium values greater than 160mEq/L in the first five days will require SAE reporting whether they require intervention or not.
5. Study patient oversight during hospitalization – We have hired four critical care research persons, two registered nurses and two respiratory therapists who together will provide 24-7 coverage for monitoring the patient's well being for the first five days of his hospital stay. This Critical Care Research Team will oversee and enforce the monitoring of the sodium levels, as well as obtain results of sodiums, CT Heads, and general information regarding the patient's condition. This team will oversee these activities at all participating OPALS sites.

Yours sincerely,

Martin Osmond, MD, CM, FRCPC
 Associate Professor, Department of Pediatrics

**CHEO Research Ethics Board
 APPROVAL**

Chair's Signature: *Carole Gentile*

Date: *November 6, 2006*



Children's Hospital of Eastern Ontario
Centre hospitalier pour enfants de l'est de l'Ontario

CHEO Research Ethics Board * FINAL APPROVAL

Principal Investigator: Dr. Martin Osmond

Proposal Number: #06/09E

Protocol Title: Hypertonic Resuscitation following Traumatic Injury

Department or PSU: Emergency

Approval date: June 14, 2006

Approval valid until: June 13, 2007

Documents reviewed and approved: REB Protocol (Revised Protocol May 29, 2006); Letter of Information & Consent Form (June 14, 2006); Investigators Brochure (Edition Number 02, June 30, 2004); Health Canada Letter of Non-objection (May 27, 2005, Control #097980)

This is to notify you that the Children's Hospital of Eastern Ontario Research Ethics Board has granted full board approval to the above named research study for a period of one year. In fulfilling its mandate, the REB is guided by the Tri-Council Policy Statement, Health Canada Division 5 of the Food and Drug Regulations, the ICH Good Clinical Practice Practices: Consolidated Guidelines; as well as the applicable laws and regulations of Ontario. The REB approval is valid until the date referenced above assuming timely and acceptable responses to the REB's periodic requests for surveillance and monitoring information. The protocol was approved at a meeting of the REB in which the quorum rules were met and only those REB members who are independent of the investigator(s) conducting the study voted on the final decision.

During the course of the research, no deviations from, or changes to, the protocol or consent form may be initiated without prior written approval from the REB except when necessary to eliminate immediate hazards to the subject. Local Serious Adverse Events (SAEs) reports must follow 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". If these changes/adverse events require a change to the information /consent document, and/or recruitment advertisement, the newly revised information/consent document, and/or advertisement, must be submitted to the office for approval. The primary investigator must produce an annual report that includes a summary of serious adverse events, any study amendments, and subject recruitment. A final report is also required at the conclusion of the trial. Finally, the primary investigator must notify the REB if one of the investigators leaves the institution or the project, and if the contractual agreement between the Sponsor and the principal investigator changes in any way.

In keeping with the REB bilingualism, informed consent forms must be available in both English and French. The policy requires that a French version of the consent form be made available within two to three months of the initial approval. However, if an investigator believes that it is impossible to meet this time line, the Board should be advised and a reasonable alternate time line proposed.

Wishing you success in your project.

Regards,

Carole Gentile
Dr. Carole Gentile, C.Psych.
Chair, Research Ethics Board

CG/sneh 14/06/06

c.c. Pat Brzeczau, Manager, CHEO Research Institute
Elsa Nesbitt, Research Coordinator

This is an official document. Please retain the original for your files.

Version 01/04

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Tel: (613) 737-7600 www.chc.ca/enca

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d'Ottawa

Research Ethics Board
Conseil d'éthique en recherches
798-5555 ext 14146, 14902 or 15072
Fax No. - 761-4311
<http://www.ohri.ca/ohreb/>

Wednesday, November 22, 2006

Dr. Ian Stiell
The Ottawa Hospital - Civic Campus
Ottawa Health Research Institute
Clinical Epidemiology Program, F6
Ottawa, ON
K1Y 4E9

Dear Dr. Stiell:

Re: Protocol # 2005375-01H Hypertonic Resuscitation Following Traumatic Injury

Thank you for your letter of November 13, 2006, Jane Banek's letter of November 16, 2006 and the emails of November 22, 2006 from Cathy Clement and Angela Marcantonio regarding the above study.

We acknowledge receipt of the letter of November 7, 2006 from Eileen Bulger from the ROC Clinical Trial Center enclosing the Hospital Protocol for Sodium Monitoring and the fax copy of the letter from the Director of the Department of Health & Human Services, Rockville MD.

The Protocol Amendment IND 12505 & 12506 dated October 28, 2006 and the English Information For Care Providers letter received November 22, 2006 are approved.

Ethical approval remains in effect until June 6, 2007.

Yours sincerely,

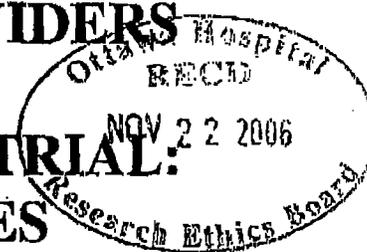
Raphael Saginur, M.D.
Chairman
Ottawa Hospital Research Ethics Board

RS/ps

Encl.

INFORMATION FOR CARE PROVIDERS

HYPERTONIC RESUSCITATION TRIAL: RESUSCITATION OUTCOMES CONSORTIUM



This patient has been enrolled in a prehospital hypertonic fluid resuscitation trial sponsored by the Resuscitation Outcomes Consortium. He/She has received 250cc of either 7.5% saline/6% dextran, 7.5% saline w/o dextran, or normal saline administered by the prehospital provider. Administration of the blinded study intervention was completed before the patient was transferred to the care of hospital staff in the emergency department of your hospital. No further intervention is required in the hospital but we want you to be aware of the following issue:

As a result of this treatment, the patient could have a transient rise in serum sodium. Previous studies suggest that the average sodium on admission to the hospital ranges from 147 to 155mEq/L and these values should normalize by 12 hours. We do not recommend that you intervene for this small initial rise in serum sodium as this is expected and required for the study intervention to be effective. The study requires that you monitor the following the serum sodium every 8 hours over the first 24 hours. An initial rise in serum sodium beyond 160mEq/L over the first 12 hours, a persistently elevated serum sodium beyond 12 hours, or a subsequent rise in serum sodium after admission should *not* be presumed to be due to the study intervention and another etiology should be sought and appropriate treatment instituted.

Patients with severe traumatic brain injury are at risk for the development of central diabetes insipidus early after injury, and thus this diagnosis should be considered in this patient cohort.

Should you have any questions regarding this study, please do not hesitate to contact your local ROC investigator or coordinator.

Dr. Ian Stiell
The Ottawa Hospital
Tel: 613-274-9754

Dr. Martin Osmond
The Children's Hospital of
Eastern Ontario
Tel: 613-737-7600 ext. 2318

{Valid until June 7, 2007}



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d'Ottawa

Research Ethics Board
Conseil d'éthique en recherches
798-5555 ext 14146, 14902 or 15072
Fax No. ~ 761-4311
<http://www.ohri.ca/ohreb/>

Wednesday, May 24, 2006

Dr. Ian Stiell
The Ottawa Hospital - Civic Campus
Ottawa Health Research Institute
Clinical Epidemiology Program, F6
Ottawa, ON
K1Y 4E9

Dear Dr. Stiell:

RE: Protocol# - 2005375-01H Hypertonic Resuscitation Following Traumatic Injury

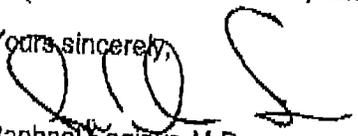
Renewal Expiry Date - Wednesday, June 06, 2007

Thank you for the letters from Jane Banek dated May 17 and 23, 2006. I am pleased to inform you that your Annual Renewal Request (listed above), the revised English Information Sheet Version 5.1 dated May 23, 2006, the revised French Information Sheet Version 5.1 dated May 22, 2006 and the Protocol Amendment dated May 11, 2006 were reviewed by the Ottawa Hospital Research Ethics Board (OHREB) and are approved. No changes, amendments or addenda may be made in the protocol or the consent form without the OHREB's review and approval.

Renewal is valid for a period of one year. The validation date should be indicated on the bottom of all consent forms and information sheets (see attached copy). Approximately one month prior to that time, a single renewal form should be sent to the OHREB office.

The Tri-Council Policy Statement requires a greater involvement of the OHREB in studies over the course of their execution. As well, you must inform the Board of adverse events encountered during the study, here or elsewhere, or of significant new information which becomes available after the Board review, either of which may impinge on the ethics of continuing the study. The OHREB will review the new information to determine if the protocol should be modified, discontinued, or should continue as originally approved.

Yours sincerely,


Raphael Saginur, M.D.
Chairman
Ottawa Hospital Research Ethics Board

Encl.

/p



The Ottawa Hospital L'Hôpital
d'Ottawa

Research Ethics Board
Conseil d'éthique en recherches
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Friday, March 03, 2006

Dr. Ian Stiell
The Ottawa Hospital - Civic Campus
Ottawa Health Research Institute
Clinical Epidemiology Program, F6
Ottawa, ON
K1Y 4E9

Dear Dr. Stiell:

Re: Protocol # 2005375-01H Hypertonic Resuscitation Following Traumatic Injury

Thank you for your letter of February 8, 2006. We have revised our file to show the start date as April 1, 2006. The revised Protocol dated (11/08/2005) November 8, 2005 and the revised English and French Information Sheets, version 4, dated February 2, 2006 are approved.

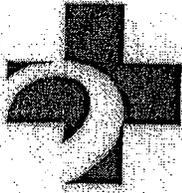
Ethical approval remains in effect until June 6, 2006.

Yours sincerely,

Raphael Saginur, M.D.
Chairman
Ottawa Hospital Research Ethics Board

RS/ps

Encl.



The Ottawa Hospital | L'Hôpital
Hospital | d'Ottawa

Research Ethics Board
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<http://www.ohri.ca/ohreb/>

initial approval

Tuesday, August 30, 2005

Dr. Ian Stiell
The Ottawa Hospital - Civic Campus
Ottawa Health Research Institute
Clinical Epidemiology Program, F6
Ottawa, ON
K1Y 4E9

Dear Dr. Stiell:

Re: Protocol # 2005375-01H Hypertonic Resuscitation Following Traumatic Injury
Protocol approval valid until - Tuesday, June 06, 2006

The above listed protocol was reviewed by the full Board of the Ottawa Hospital Research Ethics Board (OHREB) at the meeting held on June 7, 2005. You have met the requirements of the OHREB and your protocol has been granted approval by the OHREB. Approval is for the Protocol Draft 5/16/2005, the Investigator's Brochure for RescueFlow (Edition No. 02) release date June 30, 2004, the English Glasgow Outcome Scale, the French and English Information Sheets both dated (version 3) July 20, 2005, and the French and English Telephone consent. No changes, amendments or addenda may be made in the protocol or the consent form without the OHREB's review and approval.

The validation date should be indicated on the bottom of all consent forms and information sheets (see copy attached). Approximately six weeks prior to that time, a single renewal form should be sent to the OHREB Office.

The Tri-Council Policy Statement requires a greater involvement of the OHREB in studies over the course of their execution. You must inform the Board of adverse events encountered during the study, here or elsewhere, or of significant new information which becomes available after the Board review, either of which may impinge on the ethics of continuing the study. The OHREB will review the new information to determine if the protocol should be modified, discontinued, or should continue as originally approved.

Yours sincerely,


Francine F.A. Sarazin, Ph.D., C.Psych.
Vice-Chairman
Ottawa Hospital Research Ethics Board

Encl.

/cb



To: Dr. A. Affleck
 From: Bev Junnila, Chair RET
 Subject: Hypertonic Resuscitation Following Traumatic Injury (RET#41.05)
 Date: January 8, 2007

The Thunder Bay Regional Health Sciences Centre RET has conducted a review of the research protocol that is referenced above, and has approved the involvement of human subjects as specified in the protocol. The quorum for approval was free from conflict and did not involve any member that is associated with this project.

The Thunder Bay Regional Health Sciences Centre Research Ethics Team is guided by the policies and ethical standards put forth by the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects as well as the ICH Good Clinical Practice (GCP) guidelines.

Should your study continue for more than one year, you must submit a progress report and request a renewal a minimum of three (3) weeks before the renewal date that is specified below. Please note that approval for this study will expire on this date unless the TBRHSC RET is otherwise notified.

If, during the course of your research, there are any changes in the approved submission or any new information that must be considered with respect to the study, these should be brought to the immediate attention of the Research Ethics Team.

Type of Review

- Reviewed at Full Board Meeting-Dec. 18, 2006
- Reviewed by Chair with notification to all Board Members

Type of Submission and Version Date

Protocol: Initial Amendment - Oct 28, 2006

Outcome: Approved Received Revisions Required Not Approved

Consent: Initial Revision

Outcome: Approved Received Revisions Required Not Approved

Investigator Initial
 Brochure: Amendment

Outcome: Approved Received Revisions Required Not Approved

Other-Correspondence Nov 15, 2006 with Information for Care Providers

Outcome: Approved Received Revisions Required Not Approved

Annual Reapproval:

Renewal Date: _____

Bev Junnila

Chair, Thunder Bay Regional Health Sciences Centre RET

JAN 08 2007

Date



To: Dr. A. Affleck
From: Bev Junnila, Chair RET
Subject: Resuscitation Outcomes Consortium Hypertonic Saline Study
Date: June 27, 2006

The Thunder Bay Regional Health Sciences Centre RET has conducted a review of the research protocol that is referenced above, and has approved the involvement of human subjects as specified in the protocol. The quorum for approval was free from conflict and did not involve any member that is associated with this project.

The Thunder Bay Regional Health Sciences Centre Research Ethics Team is guided by the policies and ethical standards put forth by the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects as well as the ICH Good Clinical Practice (GCP) guidelines.

Should your study continue for more than one year, you must submit a progress report and request a renewal a minimum of three (3) weeks before the renewal date that is specified below. Please note that approval for this study will expire on this date unless the TBRHSC RET is otherwise notified.

If, during the course of your research, there are any changes in the approved submission or any new information that must be considered with respect to the study, these should be brought to the immediate attention of the Research Ethics Team.

Type of Review

- Reviewed at Full Board Meeting-June 19, 2006
- Reviewed by Chair with notification to all Board Members

Type of Submission and Version Date

- Protocol:
- Protocol Modification Summary March 20, 2006
 - Amendment 11/08/2005 with appendices A-I

Outcome: Approved Received Revisions Required Not Approved

- Consent:
- Initial
 - Revision Information Sheet Version 5.1 May 5, 2006

Outcome: Approved Received Revisions Required Not Approved

- Investigator
Brochure:
- Initial
 - Amendment

Outcome: Approved Received Revisions Required Not Approved

Other-

Outcome: Approved Received Revisions Required Not Approved

Annual Reapproval:

Renewal Date:

Bev Junnila
Chair, Thunder Bay Regional Health Sciences Centre RET

August 18/2006
Date



To: Dr. Andrew Affleck
 From: Bev Junnila, Chair RET
 Subject: Hypertonic Resuscitation Following Traumatic Injury (RET #41.05)
 Date: December 20, 2005

The Thunder Bay Regional Health Sciences Centre RET has conducted a review of the research protocol that is referenced above, and has approved the involvement of human subjects as specified in the protocol. The quorum for approval was free from conflict and did not involve any member that is associated with this project.

The Thunder Bay Regional Health Sciences Centre Research Ethics Team is guided by the policies and ethical standards put forth by the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects as well as the ICH Good Clinical Practice (GCP) guidelines.

Should your study continue for more than one year, you must submit a progress report and request a renewal a minimum of three (3) weeks before the renewal date that is specified below. Please note that approval for this study will expire on this date unless the TBRHSC RET is otherwise notified.

If, during the course of your research, there are any changes in the approved submission or any new information that must be considered with respect to the study, these should be brought to the immediate attention of the Research Ethics Team.

Type of Review

- Reviewed at Full Board Meeting-October 17, 2005
- Reviewed by Chair with notification to all Board Members

Type of Submission and Version Date

- Protocol: Initial – September 9, 2005
 Amendment

Outcome: Approved Received Revisions Required Not Approved

- Information Sheet: Initial-Version 3 December 19, 2005
 Revision

Outcome: Approved Received Revisions Required Not Approved

- Investigator Brochure: Initial – Edition 02 2004 June 30
 Amendment

Outcome: Approved Received Revisions Required Not Approved

Other-Appendix A,B,C,D,E,F,G,H, Letter December 1, 2005

Outcome: Approved Received Revisions Required Not Approved

Annual Reapproval:

Renewal Date: December 2006

Bev Junnila

Chair, Thunder Bay Regional Health Sciences Centre RET

DEC 20 2005

Date

THUNDER BAY REGIONAL HEALTH SCIENCES CENTRE

RESEARCH ETHICS TEAM

initial approval

RESEARCH ETHICS AGREEMENT

RESEARCH PROTOCOL TITLE: Hypertonic Resuscitation Following Traumatic Injury

Approval by the Thunder Bay Regional Health Sciences Centre Research Ethics Team to conduct research at the Thunder Bay Regional Health Sciences Centre is limited to the conditions and details outlined within the Protocol (September 9, 2005), Information Sheet (Version 4, December 19, 2005).

I agree to abide to the ethical guidelines and procedures of the Thunder Bay Regional Health Sciences Centre Research Ethics Team, the Tri-Council Policy Statement and my professional standards. I am aware of my responsibility to be familiar with these standards.

agree:

*That all confidential information received or exchanged will be held in strict confidence. Confidential information will be extracted in the way described and approved in the protocol. Confidential information will not be used for any purpose other than for the project for which it was provided. The data will be shared only with those individuals listed who are working directly on the project. Confidential information will be kept in a secure physical location to which access is given only to the individuals listed. The confidential information disclosed will in no way be used for computer linkage to any other existing database(s).

*That approval from the Research Ethics Team must be granted prior to any departures from this protocol or consent. The principal investigator assumes full responsibility for this study as detailed and will notify the Research Ethics Team should any unexpected results, serious adverse events, or complaints arise. Any new information learned about potential risks must also be communicated (i.e., information concerning risks learned from new publications or from other current research projects).

There will be notification to the RET should there be any change in the methodology or status of the research project during the life of this research.

*To submit a progress report (Annual Reapproval Status Form-Form D) in writing to the REB annually and upon completion of the research project.

Annual Approval required by: December 2006
Date

The undersigned hereby agrees to these terms:

AM/lek
Signature of the Principal Investigator

Dec 27/05
Date

AFFLEK
Print Name of Principal Investigator

Completed form sent to:

Mary Jane Kurm, Patient Care Services-Room 2159-2nd Level
Thunder Bay Regional Health Sciences Centre
980 Oliver Road
Thunder Bay, ON P7B 6V4
Phone: 684-6422 Fax: 684-5904 e-mail: kurmm@tbh.net

¹Individuals identified on Access to Information form

b)



DECISION BY RESEARCH ETHICS COMMITTEE

PRINCIPAL INVESTIGATOR: TO COMPLETE THE TOP PORTION OF THE FORM

RESEARCH TITLE: Hypertonic Resuscitation Following Traumatic Injury, Protocol Amendment IND 12505 and 12506.

Name of Principal Investigator: Dr. Paul Colella

- Check where applicable
- Initial Approval of Protocol Version date: _____
 - Initial Approval of Consent Version date: _____
 - Revised Informed Consent dated: _____
 - Approval of Amendment(s) and/or Revision(s) No. IND 12505 and 12506 date: November 28, 2006
 - Investigator's Brochure Version date: _____
 - Annual Renewal dated: _____
 - Serious Adverse Events (Include Data Safety Monitoring Committee Results) _____
 - Interim/Final Analysis (circle) _____
 - Other (Information letter Patient/physician/advertisements) _____

FOR USE BY CHAIRPERSON or DELEGATE

The above item was reviewed: by Full REC or as an Expedited Review
The above item was submitted to the Research Ethics Board and was:

- Approved
- Approved with revisions
- Not Approved
- Received for information

[Signature] JAN 08 2007
Chair, Research Ethics Committee Date

This Research Ethics Committee is organized and operates according to:
1) ICH (International Conference) Harmonized Tripartite Guidelines: "Good Clinical Practice (GCP) Consolidated Guidelines" and
2) The Council Policy Statement "Ethical Conduct for Research Involving Humans"
Revised: September 25, 2006



HÔPITAL RÉGIONAL DE
SUDBURY
REGIONAL HOSPITAL

**EXPEDITED REVIEW
DECISION BY THE RESEARCH ETHICS COMMITTEE**

PRINCIPAL INVESTIGATOR: TO COMPLETE THE TOP PORTION OF THE FORM

Hypertonic Resuscitation Following Traumatic Injury

Check where applicable:

- Initial Approval of Protocol Dated: _____
 - Original Informed Consent Dated: _____
 - Revised Informed Consent Dated: _____
 - Administrative Changes
(for Approved Research, Investigators Brochures...) _____
 - Annual Renewal Dated: _____
- XX Affirmation of Conditions of Approval _____

Principal Investigator: Dr. Paul Colella

Date: May 25, 2006

FOR USE BY THE EXPEDITED REVIEWER

Eligibility Criteria include:

- New research protocol with minimal risk e.g. charts reviews.
- Review of patient records by hospital personnel or authorized health research partners.
- Annual renewal of an expedited approved project.
- Administrative change in Approved Research Protocols and Investigator's Brochures
- Affirmation of "conditions of approval" have been met

Comments of Reviewer

Recommendation of Reviewer:

- Approved
- Approved with revisions (as attached)
- Not approved

Reviewer: *Meta Kline* Date: 15/6/06

The Research Ethics Committee is organized and operates according to:

- i) ICH (International Conference) Harmonized Tripartite Guideline: "Good Clinical Practice (GCP) Consolidated Guideline" and
- ii) Tri-Council Policy Statement "Ethical Conduct for Research Involving Humans"

Hotel-Dieu Grace Hospital
Research Ethics Board

Revised - Jan. 2006

ANNUAL RENEWAL REQUEST

REB number: 05- JU -008

Research project title: Hypertonic Resuscitation Following Traumatic Injury

Principal investigator: Dr. Paul Bradford

Please provide a summary of research activity in the last year.

- a. For all sites - with specific reference to any adverse events:
There are nine patients in total enrolled to date in the whole ROC Consortium.
No adverse events have been reported to date.
- b. For this particular site - with specific references to any adverse events
There have been six patients enrolled to date. We have outcomes for 4 of these patients.
No adverse events reported to date.
- c. Number of HDGH participants to date: 6
- d. Number of participants who have withdrawn - 0; and why.:

Are there any changes to funding? YES NO
(If yes, please explain):

Is funding adequate to complete the Project? YES NO

Has the hospital, medical or other staff received funding as proposed in the financial submission at study commencement? YES NO

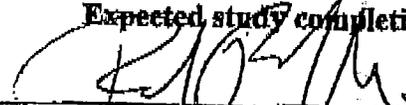
Comment:

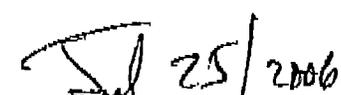
Have all modifications been submitted for approval? YES NO

Is there any concern about this project that the REB should be aware of (e.g. deviations from protocol)? YES NO

Explain:

Submission at study commencement?
Expected study completion date 2010


Principal Investigator (Signature)


Date

Hotel-Dieu Grace Hospital Research Ethics Board

Response to Submission

REB number 05-JU-008
Full Name of Study Hypertonic resuscitation following traumatic injury

Principal Investigator Bradford

Level of Review

Review date 28-Nov-06

REB meeting Date 28-Nov-06

New/revised documents included

Protocol Amendment IND 12505 & 12506; Hypertonic Resuscitation after Trauma: Resuscitation Outcomes Consortium; dated October 28, 2006

Status Approved

Comments The FDA has indicated that the study may proceed once REB approval of the above amendment is received. The amendment is approved by this REB. The study may continue.

Approval expiry date

Chairperson

Peggy O'Neil

Date: *Dec. 1, 2006*

✓ rec'd 5/8/2006

Hotel-Dieu Grace Hospital Research Ethics Board

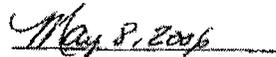
Response to Submission

REB number	05-JU-008
Protocol	
Full Name of Study	Hypertonic resuscitation following traumatic injury
Principal Investigator	Bradford
Level of Review	Expedited
Review date	05-May-06
REB meeting Date	23-May-06
New/revised documents included	Revised consent form dated May 5, 2006
Status	Approved
Comments	The revised consent form is approved for use in this study.

Approval expiry date



Chairperson


Date:

This protocol was approved by a properly constituted Research Ethics Board and in a manner consistent with applicable regulations for voting concerning the approval of the study.

Only Research Ethics Board members considered independent of the investigator(s) conducting the study participated in deliberations or voting concerning the approval of the study.

The REB is in compliance with FDA Regulations CFR Title 21, Parts 50 and 56, ICH Guidelines, and the Canadian Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans

Hôpital Hôtel-Dieu Grace Hospital
1030 Ouellette Avenue
Windsor, Ontario N9A 1B1
Tel: (519)973-4444

initial approval

August 3, 2005

Dr. Paul Bradford
Base Hospital
Hotel-Dieu Grace Hospital

Dear Dr. Bradford:

Re: REB #05-JU-008 - "Hypertonic Resuscitation following Traumatic Injury"

I am pleased to tell you that the above research proposal has been approved by the Research Ethics Board for a period of one year. The appropriate hospital officials have approved and signed the Research Agreement.

The study will be reviewed annually by the Research Ethics Board (expiry date is July 2006). You will receive a reminder approximately a month before the renewal is due.

I am enclosing a copy of the signed Research Agreement for your files.

Please contact me anytime if I can be of assistance in any way.

Best wishes with your study!

Sincerely,

Peggy Oldfield

Peggy Oldfield
Interim REB Chair

PO:pa
Enclosure

The REB is in compliance with FDA Regulations CFR Title 21, Parts 50 and 56, ICH Guidelines, and the Canadian Medical Research Council Guidelines for Research Ethics Boards.

Compassionate Hearts  *Competent Hands*

An Alliance of the Religious Hospitaliers of St. Joseph and The Salvation Army