

<b>ROC Site Status &amp; Enrollment as of 4/30/2007</b>							
	Toronto	REB	Initial REB Approval	REB Approval for Final Protocol	REB Approval for FDA Amendment	Shock Cohort Enrolled	TBI Cohort Enrolled
	<b>Overarching REB-Sunnybrook &amp; Women's College Receiving Hospitals</b>					16	38
	Hamilton Health Sciences includes:						
	Hamilton General Hospital	Hamilton Hlth Sci	3/21/2006	4/18/2006	11/22/2006		
	McMaster Children's Hospital	Hamilton Hlth Sci	3/21/2006	4/18/2006	11/22/2006		
	Hospital for Sick Children	Hospital for Sick Kids	7/24/2006	7/24/2006	11/20/2006		
	St Michael's Hospital	St. Michael's Sunnybrook	1/27/2006	4/13/2006	11/20/2006		
	Sunnybrook & Women's College-Sunnybrook	Sunnybrook	11/16/2005	4/10/2006	11/17/2006		
	<b>EMS Services</b>						
	Hamilton Emergency Services	Hamilton Hlth Sci	3/21/2006	4/18/2006	11/22/2006		
	Ontario Air Ambulance Base Hospital Program	Sunnybrook	11/16/2005	4/10/2006	11/17/2006		
	Toronto EMS Headquarters	Sunnybrook	11/16/2005	4/10/2006	11/17/2006		
	All agencies are enrolling						
	*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						

Shock Enrollment Breakdown as of 4/30/2007														
EMS Agencies/Hospitals	Hamilton General Hospital	McMaster Children's Hospital	Hospital for Sick Children	St Michael's Hospital	Sunnybrook & Women's College-Sunnybrook	Non-ROC	Pre-Hosp Disposition Unknown	Ottawa Hospital, Civic Site	London Health Sciences, Ottawa Hosp	Sudbury Regional, Ottawa Hospital	LHSC Victoria, Ottawa Hospital	LHSC University Ottawa Hospital	Hotel Dieu Grace, Ottawa Hospital	Total
	4	0	0	0	0	1*	0	0	0	0	0	0	0	5
Hamilton Emergency Services	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Ontario Air Ambulance Base Hospital Program	1	0	0	5	4	0	0	0	0	0	0	0	0	10
Toronto EMS Headquarters	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total for Hospital	5	0	0	5	4	1	0	1	0	0	0	0	0	16

\*Air agency stopped briefly at non-ROC hospital to secure airway/intubate. Pt then transported by Air agency to ROC Ottawa Hospital-Children's Hospital of Western Ontario

TBI Enrollment Breakdown as of 4/30/2007														
EMS Agencies/Hospitals	Hamilton General Hospital	McMaster Children's Hospital	Hospital for Sick Children	St Michael's Hospital	Sunnybrook & Women's College-Sunnybrook	Non-ROC	Pre-Hosp Disposition Unknown	Ottawa Hospital, Civic Site	London Health Sciences, Ottawa Hosp	Sudbury Regional, Ottawa Hospital	LHSC Victoria, Ottawa Hospital	LHSC University Ottawa Hospital	Hotel Dieu Grace, Ottawa Hospital	Total
	3	0	0	2	11	1*	1	2	1	1	2	1	1	3
Hamilton Emergency Services	0	0	0	1	8	0	0	0	0	0	0	0	0	26
Ontario Air Ambulance Base Hospital Program	0	0	0	0	0	0	0	0	0	0	0	0	0	9
Toronto EMS Headquarters	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total for Hospital	6	0	0	3	19	1	1	2	1	1	2	1	1	38

\*Protocol violation; no shock or penetrating trauma; will still be followed for safety



**RESEARCH ETHICS BOARD**

**ANNUAL PROGRESS REPORT**

*Research Ethics Board Review of an Active Study  
(to be completed by REB Chair only)*

**REB Project #: 06-108**

**Principal Investigator: Dr. Michelle Welsford**

**Project Title Resuscitation Outcomes Consortium (ROC) Hypertonic Saline Trial**

- Approved for Continuation**
- Approved conditional on changes noted in "Conditions" section below**

**Type of Approval:**

- Full Research Ethics Board**
- Research Ethics Board Executive**

**REB Approval Period: One Year from the Date of This Approval Letter**

- New Enrolment Suspended**
- Suspended pending further review**

**Conditions:**

The Hamilton Health Sciences/McMaster University 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 and Division 5 Health Canada Food and Drug Regulations.

\_\_\_\_\_  
Signature of Research Ethics Board Chair

20 March, 2007  
Date of REB Meeting

F. Jack Holland, MD, FRCP, FRCP(C), Chair  
Hamilton Health Sciences/McMaster Health Sciences Research Ethics Board

All Correspondence should be addressed to the REB Chair and forwarded to:  
REB Coordinator, Hamilton Health Sciences  
1057 Main Street West, Suite 1, Hamilton ON L8S 1B7  
Tel. 905-521-2100 Ext. 42013 Fax: 905-577-8379



**RESEARCH ETHICS BOARD**



REB Office, 1057 Main St. W., Hamilton, ON L8S 1B7  
 Telephone: 905-521-2100, Ext. 42013  
 Fax: 905-577-8379

**Research Ethics Board  
 Membership**

- Jack Holland MD FRCP FRCP(C)  
Chair
- Suzette Sakuma PhD  
Vice-Chair/Ethics Representative
- Mary Bedek CCHRA (C)  
Privacy Officer
- Morris Blajchman MD FRCP(C)  
Hematology
- Julie Caruthers MLT  
Research, Transfusion Medicine
- David Clark MD PhD FRCP(C)  
Medicine
- Jean Crowe MHS  
Rehabilitation Science
- Malcolm Curtis BA BEd MEd  
Community Representative
- Kavita Dharmapalakar MD  
Diagnostic Imaging
- Lynn Donohue BA(Hons)  
Community Representative
- Brock Easterbrook BA  
Research Coordinator, Anaesthesia
- Sylvia Fung BSP LLB  
Pharmacy/Legal
- Melanie Griffiths FRCR (UK)  
Diagnostic Imaging
- Cindy James BScN  
Gastroenterology
- Jan Jones MD FRCP FRCP(C)  
Medicine
- Rosanne Kent RN BA MHSc(M)  
Cardiology
- Madhu Natarajan MD, FRCP, FACC  
Cardiology
- Jasim Radhi MB FRCP, FRCP(C)  
Anatomical Pathology
- Kesava Reddy MB BS FRCS FACS  
Neurosurgery
- Susan Shannon BA MSc PhD  
Clinical Epidemiology & Biostatistics
- Gita Sohli BSc Pharm  
Pharmacy
- Marie Townsend BA(Hons), MBA  
Administration
- Graham Turple MD FRCP(C)  
Medicine
- Alison van Nie MEd  
Research Ethics Officer
- Jeff Weisz MD FRCP(C) FACP  
Medicine
- Jim Wright BSc MD  
Radiation Oncology
- Ed Youngblat PhD  
Obstetrics/Gynecology

The HHS/FHS REB operates in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans; the Health Canada / ICH Good Clinical Practice: Consolidated Guidelines (GCP); and the applicable laws and regulations of Ontario. The membership of this REB also complies with the membership requirements for REBs as defined in Canada's Food and Drug Regulations (Division 5: Drugs for Clinical Trials Involving Human Subjects).

November 22 2006

**PROJECT NUMBER:** 06-108  
**PROJECT TITLE:** Hypertonic Resuscitation Following Traumatic Injury  
**PRINCIPAL INVESTIGATOR:** Dr. M. Welsford

This will acknowledge receipt of Protocol Amendment IND 12505 and 12506 and the revised information for Care Providers (Hamilton Health Sciences) along with information regarding the temporary suspension of enrolment in the above-named study as of October 26, 2006 due to questions raised by the US FDA.

The REB Executive has reviewed and approved the following documents that the FDA is now satisfied with:

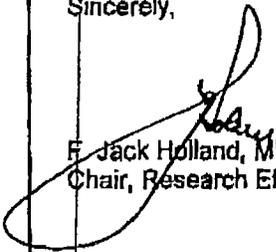
- Protocol Amendment IND 12505 & 12506
- Information for Care Providers (Hamilton Health Sciences)

The REB approves of this study being restarted at Hamilton Health Sciences.

We wish to advise the Research Ethics Board operates in compliance with ICH Good Clinical Practice Guidelines and the Tri-Council Policy Statement.

**PLEASE QUOTE THE ABOVE-REFERENCE PROJECT NUMBER ON ALL FUTURE CORRESPONDENCE**

Sincerely,

  
 F. Jack Holland, MD, FRCP, FRCP (C)  
 Chair, Research Ethics Board



*Initial*

Hamilton Health Sciences  
EXEMPLARY CARE • ACADEMIC EXCELLENCE

**RESEARCH ETHICS BOARD**

**AMENDMENT REQUEST**

REB Project #: 06-108

Locally Responsible Investigator: Dr. Michelle Welsford

Title of Study: Resuscitation Outcomes Consortium (ROC) Hypertonic Saline Trial

Document(s) Amended with version # and date:

- > Protocol - Revised protocol
- > Information/Consent - Patient Study Notification Version 5 (Both cohorts)
- > Other (Specify:) - No Objection Letter from Health Canada

**Research Ethics Board Review**  
*(this box to be completed by REB Chair only)*

Amendment approved as submitted

Amendment approved conditional on changes noted in "Conditions" section below

New enrolment suspended

Study suspended pending further review

**Level of Review:**

Full Research Ethics Board

Research Ethics Board Executive Committee

**Conditions:**

The Hamilton Health Sciences/McMaster Health Sciences 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.

F. Jack Holland, MD, FRCP, FRCP(C), Chair  
Hamilton Health Sciences/McMaster Health Sciences Research Ethics Board

18 April, 2006  
Date of REB Meeting

All Correspondence should be addressed to the REB Chair and forwarded to:  
REB Coordinator, Hamilton Health Sciences  
1057 Main Street West, Suite 1, Hamilton ON L8S 1B7  
Telephone: 905-521-2100, ext. 42013  
Fax: 905-577-8379



## RESEARCH ETHICS BOARD

March 29, 2006

**PROJECT NUMBER:** 06-108  
**PROJECT TITLE:** Resuscitation Outcomes Consortium (ROC)  
Hypertonic Saline Trial  
**PRINCIPAL INVESTIGATOR:** Dr. M. Welsford

As you are aware your study was presented at the March 21, 2006 Research Ethics Board meeting where it received *final* approval from the full REB. The protocol submission and all appendices were found to be acceptable on both ethical and scientific grounds.

We are pleased to issue final approval for the above-named study for a period of 12 months from the date of the REB meeting on March 21, 2006. Continuation beyond that date will require further review and renewal of REB approval. Any changes or amendments to the protocol must be approved by the Research Ethics Board.

We wish to advise the Research Ethics Board operates in compliance with ICH Good Clinical Practice Guidelines and the Tri-Council Policy Statement.

Investigators in the Project should be aware that they are responsible for ensuring that a complete consent form is inserted in the patient's health record. In the case of invasive or otherwise risky research, the investigator might consider the advisability of keeping personal copies.

A condition of approval is that the physician most responsible for the care of the patient is informed that the patient has agreed to enter the study. Any failure to meet this condition means that Research Ethics Board approval for the project has been withdrawn.

PLEASE QUOTE THE ABOVE-REFERENCED PROJECT NUMBER ON ALL  
FUTURE CORRESPONDENCE

Sincerely,

F. Jack Holland, MD, FRCP, FRCP(C)  
Chair, Research Ethics Board

/dm

**All correspondence should be addressed to the REB Chair and forwarded to:  
REB Coordinator, Hamilton Health Sciences, REB Office  
1057 Main Street West, Suite 1  
Hamilton ON L8S 1B7  
Telephone: 905-521-2100, Ext. 42013  
Fax: 905-577-8379**



The Hospital for Sick Children  
Research Ethics Board



### Amendment Request Form

- 1- REB File Number: 1000009106
- 2- Study Title: Hypertonic Saline Dextran (HSD)  
trial ROC consortium
- 3- Describe the proposed study amendment or modification with rationale. For each item, please specify whether it is **Minor** eg, administrative changes such as deleting the name of a co-investigator, or **Major** eg, change in sponsorship that causes the investigator to have a conflict of interest, adding an intervention such as additional blood tests, or any substantive change that will be made to the consent form.  
Please note; commercial sponsors will be charged a \$500 REB review fee for amendments that require full Board review.

Please see attached letter regarding re-starting the HSD trial by the FDA.

We require approval for the new caregiver information sheet attached.

4- Science Review: Science review may be needed for major amendments. If in doubt, please take advice with the REB Office. Please attach a copy of the completed science review form.

5- Will this amendment alter the study monitoring requirements?

No

Yes (please describe) \_\_\_\_\_

6- What follow up action do you recommend for HSC study subjects who are already enrolled in the study?

- Inform study subjects ASAP
- Revise the consent/assent forms (Please attach a copy with the changes highlighted)
- Other (please describe) \_\_\_\_\_
- No action Required

7- Does this amendment alter the level of monitoring required for this study? If uncertain, please discuss with the Clinical Research Office staff; Julie Gibson or Velma Marzinotto.

Yes  No  Perhaps

8- If Health Canada approved the original protocol (effective September 2001), their approval may also be required for this proposed amendment.

If the study sponsor requires a formal letter of approval, please attach a draft letter and forward an electronic copy as well.

10- Signature of Primary Investigator: \_\_\_\_\_

Date

Nov. 17/06

11- Signature(s) of Co-Investigator(s)\* \_\_\_\_\_ Date \_\_\_\_\_  
\*for Major amendments only

12- Signature of Clinical Chief \_\_\_\_\_ Date 11/17/06  
or Supervisor

13- Approved & Signature of REB Chair M. Friedman Date NOV 20 2006



# Research Ethics Board (REB)

*The REB is organized and operates according to the principles and practices stated in the Declaration of Helsinki, the Canadian Tri-Council Policy Statement (1998), ICH/GCP guidelines and Division 5 of the Food & Drug Regulations, Health Canada*

## Approval & Terms of Agreement

**Investigators:** Dr. Jamie Hutchison, L.Morrison  
**Project title:** Resuscitation Outcomes Consortium (ROC) Hypertonic Saline Trial  
**File number:** 100009106

**Protocol Version Date:** November 2005  
**Consent & Assent form version date:** Patient Study Notification: Version 6 July 12, 2006; Family Study Notification: Version 4, July 12, 2006; Telephone script: January 24, 2006.  
**Investigator's Brochure version date:** June 30, 2004  
**Level of Continuing Review:** III E

*I agree to carry out the proposed research involving human subjects in accordance with the protocol approved by the REB using the approved consent form/s. I shall notify the division/department head and the REB prior to implementing any amendments in the protocol and of any deviations, adverse or unexpected events as soon as possible. I certify that the research contract and corresponding protocol are consistent (where applicable) and will inform the contract manager of any proposed amendments.*

**Signature of Primary Investigator**

DATE 20/07/06

*I approve of this research protocol, agree to share responsibility for its proper conduct, and will ensure that the REB is notified of concerns, as appropriate.*

**Signature of (Division/Department Head)**

DATE 20th July, 06

*The REB of the Hospital for Sick Children has reviewed and approved the above-named project.*

**Dr. Melvin Freedman, REB Chair**  
555 University Avenue  
Toronto, Ontario, M5G 1X8  
Tel: 416-813-6152  
Fax: 416-813-5085  
Email: [melvin.freedman@sickkids.ca](mailto:melvin.freedman@sickkids.ca)

DATE OF APPROVAL JUL 24 2006

EXPIRY DATE July 2007



Research Ethics Board  
Office of Research Administration  
Telephone: 416 864-6060 Ext 2557  
Facsimile: 416 864-6043  
e-mail: [pateld@smh.toronto.on.ca](mailto:pateld@smh.toronto.on.ca)

27 January 2006

Dr Arthur Slutsky  
Vice President, Research  
St Michael's Hospital



Leading with Innovation  
Serving with Compassion

**ST. MICHAEL'S HOSPITAL**

*A teaching hospital affiliated with the University of Toronto*

Dear Dr Slutsky

Re: REB 05-234: ROC HS Trial – Hypertonic Resuscitation following Traumatic Injury

**REB APPROVAL:**

<b>Original approval Date</b>	<b>27 January 2006</b>
<b>Annual Review Date</b>	<b>27 January 2007</b>

At the St Michael's Hospital Research Ethics Board (REB) meeting held on 26 October 2005, the above referenced study was discussed and subsequently the views derived from this discussion have been documented and resolved.

The REB approves the study as it is found to comply with relevant research ethics guidelines, as well as the Ontario Personal Health Information Protection Act, 2004. The REB hereby issues approval for the above named study for a period of 12 months from the date of this letter. Continuation beyond that date will require further review of REB approval. In addition, the following documents are also hereby approved:

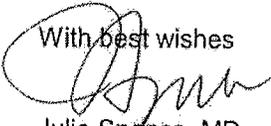
- 1 Patient Study Notification dated 24 January 2006
- 2 Family Study Notification dated 24 January 2006
- 3 ROC HS Telephone Script dated 24 January 2006

During the course of this investigation, any significant deviations from the approved protocol and/or unanticipated developments or significant adverse events should immediately be brought to the attention of the Research Ethics Board.

This letter serves as approval by the SMH REB for conduct of this study; however, additional approvals are required as outlined on the Research Administration Authorization Check List form. Enclosed is a copy of this check list and REB authorization is in the appropriate space. Also, the Clinical Trial Agreements have to be submitted to the Research Office for review and approval. The remainder of the approvals **must be** coordinated through the Research Office prior to initiation of this research. All drug dispensing must be coordinated through the Research Pharmacy at 416-864-5413.

The SMH REB operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans, the Ontario Personal Health Information Protection Act, 2004, and ICH Good Clinical Practice Consolidated Guideline E6, Health Canada's Regulations Amending the Food and Drug Regulations (1024 - Clinical Trials). Furthermore, all investigational drug trials at SMH are conducted by Qualified Investigators (as defined in the latter document).

With best wishes

  
Julie Spence MD  
Chair, Research Ethics Board

Encl:  
RH/dp

30 Bond Street  
Toronto, Ontario  
M5B 1W8  
416-360-4000  
[www.stmichaelshospital.com](http://www.stmichaelshospital.com)

*digital in the mail*

Research Ethics Board  
Office of Research Administration  
Telephone: 416 864-6060 Ext 2557  
Facsimile: 416 864-8043  
e-mail: [patekd@smh.toronto.on.ca](mailto:patekd@smh.toronto.on.ca)



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Serving with Compassion

**ST. MICHAEL'S HOSPITAL**  
*A teaching hospital affiliated with the University of Toronto*

13 April 2006

Dr Arthur Slutsky  
Vice President, Research  
St Michael's Hospital

Dear Dr Slutsky

Re: <u>REB 05-234: ROC HS Trial – Hypertonic Resuscitation following Traumatic Injury</u>		
<b>REB APPROVAL:</b>	<b>Original approval Date</b>	<b>27 January 2006</b>
	<b>Annual Review Date</b>	<b>27 January 2007</b>

Thank you for your communication of 27 February 2006 concerning amended documents regarding the above named study.

I have reviewed and hereby issue Research Ethics Board approval for the following documents as submitted:

- 1 Patient Study Notification dated 27 February 2006
- 2 Brochure submitted on 01 March 2006
- 3 Executive Summaries version dated February 2006
- 4 Lay summary version dated February 2006
- 5 Protocol Version dated November 2005

During the course of this investigation, any significant deviations from the approved protocol and/or unanticipated developments or significant adverse events should immediately be brought to the attention of the Research Ethics Board.

The SMH REB operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans, the Ontario Personal Health Information Protection Act, 2004, and ICH Good Clinical Practice Consolidated Guideline E6, Health Canada's Regulations Amending the Food and Drug Regulations (1024 - Clinical Trials). Furthermore, all investigational drug trials at SMH are conducted by Qualified Investigators (as defined in the latter document).

With best wishes

Julie Spence MD  
Chair, Research Ethics Board

JS/dp

30 Bond Street  
Toronto, Ontario  
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[www.stmichaelshospital.com](http://www.stmichaelshospital.com)



MEMORANDUM

**To:** Dr. L. Morrison  
Prehospital & Transport Medicine  
Room B103

**From:** Philip Hébert MD

**Date:** November 17, 2006

**Subject:** **Hypertonic Resuscitation Following Traumatic Injury  
ROC HS Trial**

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*Project Identification Number: 353-2005*

The Research Ethics Board is in receipt of your memo dated November 7, 2006 regarding the temporary suspension of enrolment in the above referenced study as of October 26, 2006 due to questions raised by the US FDA.

The Board has reviewed and approved the following documents that the FDA is now satisfied with:

- Protocol Amendment IND 12505 & 12506
- Information for Care Providers (Sunnybrook)

This Board approves of this study being restarted at Sunnybrook Health Sciences Centre.

During the course of the research, any significant deviations from the Approved protocol and/ or any unanticipated developments must be Brought to the attention of the Research Ethics Board.

Thank you for keeping the Board informed.



---

Thomas W. Paton Pharm D  
Vice Chair, Research Ethics Board  
/cap

MEMORANDUM

**To:** Dr. L. Morrison  
Prehospital & Transport Medicine  
Room B103

**From:** Philip Hébert MD

**Date:** April 10, 2006

**Subject:** Hypertonic Resuscitation Following Traumatic Injury  
ROC HS Trial

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*Project Identification Number: 353-2005*

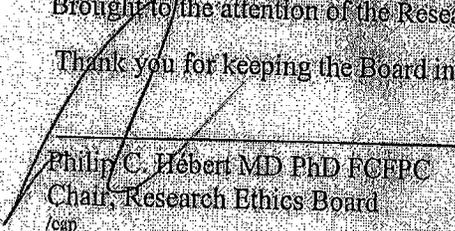
The Research Ethics Board is in receipt of your memo dated February 27, 2006 and has reviewed and approved the following documents pertaining to the above referenced study.

- Revised Protocol with appendices A-J
- FDA Approval letter dated February 16, 2006
- Patient Study Notification Version 4 (both cohorts)
- Executive Summaries (lay and professional)
- Telephone follow-up Script

This study may continue at Sunnybrook Health Sciences Centre.

During the course of the research, any significant deviations from the Approved protocol and/ or any unanticipated developments must be Brought to the attention of the Research Ethics Board.

Thank you for keeping the Board informed.

  
Philip C. Hébert MD PhD FCPC  
Chair, Research Ethics Board

/cap

# MEMORANDUM



**To:** Dr. L. Morrison  
Prehospital & Transport Medicine  
Room B103

**From:** Philip Hébert MD

**Date:** November 16, 2005

**Subject:** Hypertonic Resuscitation Following Traumatic Injury  
ROC HS Trial

**Research Ethics Board**  
*Sunnybrook Campus*

The Research Building  
2075 Bayview Avenue,  
Room S1 33,  
Toronto, ON,  
Canada M4N 3M5  
Tel 416.480.4276  
Fax 416.480.5814

The Research Ethics Board  
of Sunnybrook and Women's  
College Health Sciences  
Centre operates in compliance  
with the Tri-Council Policy  
Statement, the ICH/GCP  
Guidelines and Division 5 of  
the Food and Drug Regulations.

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*Project Identification Number: 353-2005*  
*Approval Date: November 16, 2005*

The Research Ethics Board of Sunnybrook & Women's College Health Sciences Centre has conducted a full Board review of the research protocol referenced above on the above captioned date and approved the involvement of human subjects as specified in the protocol.

The approval of this study includes the following documents:

- Family Study Notification Version 2 -- both cohorts
- Patient Study Notification Version 3 -- both cohorts
- Protocol With appendicies A-G
- Investigator's Brochure Edition 2 dated June 30, 2004

The Board is also in receipt of your memo dated October 18, 2005 and has reviewed and approved the following documents.

- Summary of ROC HS Trial (for lay audience)
- Requirements for Research Plan Section 16 for the Resuscitation Outcomes Consortium (revised with IPC Recommendations)
- Letter dated September 8, 2005 from the Information and Privacy Commissioner/Ontario

The quorum for approval did not involve any member associated with this project.



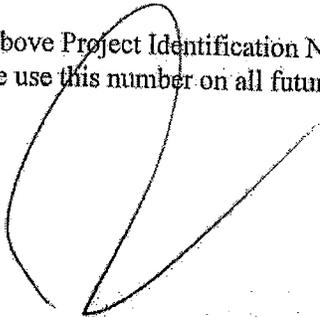
**Research Ethics Board**  
*Sunnybrook Campus*

The Research Building  
2075 Bayview Avenue,  
Room S1 33,  
Toronto, ON,  
Canada M4N 3M5  
Tel 416.480.4276  
Fax 416.480.5814

The Research Ethics Board  
of Sunnybrook and Women's  
College Health Sciences  
Centre operates in compliance  
with the Tri-Council Policy  
Statement, the ICH/GCP  
Guidelines and Division 5 of  
the Food and Drug Regulations.

Should your study continue for more than one year you must request a renewal on or before one year from the approval date. Please advise the Board of the progress of your research annually and/or any adverse reactions or deviations which may occur in the future.

The above Project Identification Number has been assigned to your project  
Please use this number on all future correspondence.



**Philip C. Hébert, MD PhD FCFPC**  
Chair, Research Ethics Board  
/cap