

Shock Enrollment Breakdown as of									
4/30/2007									
EMS Agencies/Hospitals									
British Columbia Ambulance Service		Lion's Gate Hospital	Royal Columbian Hospital	Vancouver General Hospital	Pre-hosp disposition unknown	ED unknown-no ED Admit form	Total		
		1	3	3	0	0	7		
TBI Enrollment Breakdown as of									
4/30/2007									
EMS Agencies/Hospitals									
British Columbia Ambulance Service		Lion's Gate Hospital	Royal Columbian Hospital	Vancouver General Hospital	Pre-hosp disposition unknown	ED unknown-no ED Admit form	Total		
		1	4	4	2	1	12		



PROVIDENCE HEALTH CARE
Research Institute

UBC-Providence Health Care Research
Institute
Office of Research Services
11th Floor Homby Site - SPH
c/o 1081 Burrard St.
Vancouver, BC V6Z 1Y6
Tel: (604) 806-8567
Fax: (604) 806-8568

ETHICS CERTIFICATE OF EXPEDITED APPROVAL: AMENDMENT

PRINCIPAL INVESTIGATOR: Morad Hameed	DEPARTMENT: PHCRI	UBC-PHC REB NUMBER: H05-50141
INSTITUTION(S) WHERE RESEARCH WILL BE CARRIED OUT:		
<small>Institution</small>	<small>Site</small>	
Vancouver Coastal Health (VCHRI/VCHA)	Powell River/Sunshine Coast	
Vancouver Coastal Health (VCHRI/VCHA)	Vancouver General Hospital	
Vancouver Coastal Health (VCHRI/VCHA)	Lions Gate Hospital	
Vancouver Coastal Health (VCHRI/VCHA)	UBC Hospital	
Vancouver Coastal Health (VCHRI/VCHA)	GF Strong Rehabilitation Centre	
Providence Health Care	Holy Family Hospital	
Vancouver Coastal Health (VCHRI/VCHA)	North Shore Community (Including Horseshoe Bay and up to Lions Bay)	
Vancouver Coastal Health (VCHRI/VCHA)	Richmond Health Services	
Vancouver Coastal Health (VCHRI/VCHA)	Sea to Sky Corridor (Including Bella Bella, Bella Coola, Squamish, Whistler and Pemberton)	
Providence Health Care	Mount Saint Joseph Hospital	
Children's and Women's Health Centre of BC (incl. Sunny Hill)	Children's and Women's Health Centre of BC (incl. Sunny Hill)	
Providence Health Care	St. Paul's Hospital	
Providence Health Care	St. Vincent's Hospital	
<small>Other locations where the research will be conducted:</small> Pemberton Treatment Center Whistler Diagnostic and Treatment Center		
CO-INVESTIGATOR(S): N/A		
SPONSORING AGENCIES: Canadian Institutes of Health Research National Institutes of Health		
PROJECT TITLE: Hypertonic Resuscitation Following Traumatic Injury		

REMINDER: The current UBC-PHC REB approval for this study expires: January 23, 2007

AMENDMENT(S):	AMENDMENT APPROVAL DATE: January 3, 2007	
<small>Document Name</small>	<small>Version</small>	<small>Date</small>
Protocol:		
Amendment 1 Summary	N/A	January 2, 2007
BC ROC In-Hospital Monitoring Plan	Version 1	January 2, 2007
Hypertonic Resuscitation Following Traumatic Injury Protocol Amendment October 28/06	N/A	October 28, 2006
Questionnaire, Questionnaire Cover Letter, Tests:		
Hospital Notice of Patient Enrollment	Version 2	January 2, 2007

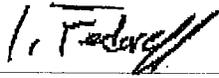
www.bcroc.com

CERTIFICATION:

1. The membership of the UBC-PHC REB complies with the membership requirements for research ethics boards defined in Part C Division 5 of the Food and Drug Regulations of Canada.
2. The UBC-PHC REB carries out its functions in a manner fully consistent with Good Clinical Practices.
3. The UBC-PHC REB has reviewed and approved the research project named on this Certificate of Approval including any associated consent form and taken the action noted above. This research project is to be conducted by the principal investigator named above at the specified research site(s). This review of the UBC-PHC REB have been documented in writing.

The amendment(s) for the above-named project has been reviewed by the UBC-PHC Research Ethics Board Chair or Associate Chair, as presented in the documentation and the accompanying documentation was found to be acceptable on ethical grounds for research involving human subjects.

Approval of the UBC-PHC Research Ethics Board or Associate Chair, verified by the above signature of one of the following:



**Dr. I. Fedoroff,
Chair**



**Dr. A. McLeod,
Associate Chair**



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UBC/Providence Health Care
OFFICE OF RESEARCH SERVICES
11th Floor Hornby Site - SPH
c/o 1081 Burrard St, Vancouver, BC V6Z 1Y6
Phone: (604) 806-8567 Fax: (604) 806-8568

Certificate of Research Ethics Board Approval Amendment

Principal Investigator: Dr. Morad Hameed	Department: Trauma Special Care Unit/Emergency Dept	Reference Number: P05-0141
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Institution(s) Where Research Will be Carried Out:
St. Paul's Hospital

Co-investigators:
Drs. J. Christenson, Abu-Laban, Ms. Pennington, Ms. Boychuk, Mr. Andrusiak, Mr. Twaites, Mr. Chute

Sponsoring Agencies:
NIH and CIHR

Project Title:
Hypertonic Resuscitation Following Traumatic Injury

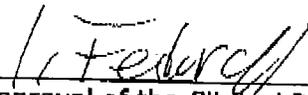
Date of Initial Approval January 23, 2006	Term of Initial Approval 1 Year	Amendment Approved: MAR 3 1 2006
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Documents Included in this Approval:
Protocol (November 3, 2005); Protocol Modification Summary (March 1, 2006); Consent for TBI Follow Up (Version 3 – February 21, 2006); Enrollment Notification Letter to Patient (Version 2 – February 21, 2006); Enrollment Notification Letter to Family (Version 2 – February 21, 2006); Family Notification Letter (Version 1 – September 21, 2005); FDA IND 12505 Approval Letter dated February 16, 2006

The Chair/Associate Chair of the UBC/PHC REB has reviewed the amendment(s) for the above-named project and the accompanying documentation was found to be acceptable on ethical grounds for research involving human subjects.

The REB approval period for this amendment expires on the one-year anniversary date of the REB approval for the entire study.

- CERTIFICATION**
In respect of clinical trials:
1. The membership of this Research Ethics Board complies with the membership requirements for Research Ethics Boards as defined in part C Division 5 of the *Food and Drug Regulations*.
 2. This Research Ethics Board carries out its functions in a manner consistent with Good Clinical Practices and
 3. This Research Ethics Board has reviewed and approved the clinical trial protocol and informed consent form for the trial, which is to be conducted by the qualified investigator named above at the specified clinical trial site. This approval and the views of this Research Ethics Board have been documented in writing.


 Approval of the Clinical Research Ethics Board by one of:
 Dr. I. Fedoroff, Chair
 Dr. A. McLeod, Associate Chair
 Date: **MAR 3 1 2006**



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11th Floor Hornby Site - SPH
c/o 1081 Burrard St, Vancouver, BC V6Z 1Y6
Phone: (604) 806-8567 Fax: (604) 806-8568

Certificate of Final Approval

Principal Investigator: Dr. Morad Hameed		Department: Trauma Special Care Unit / Emergency Department	Reference Number: P05-0141
Co-Investigators: Drs. J. Christenson, Abu-Laban, Ms. Pennington, Ms. Boychuk, Mr. Andrusiak, Mr. Twaites, Mr. Chute			
Sponsoring Agencies: NIH and CIHR			
Project Title: Hypertonic Resuscitation Following Traumatic Injury			
Date Submitted: June 7, 2005	Date Ethical Approval: January 23, 2006	Date Final Approval: JAN 24 2006	
<p>The UBC/PHC Research Ethics Board has granted ethical approval for the above-referenced research project. I am pleased to inform you that all necessary approvals and agreements/contracts are now in place and that you have permission of the hospital to begin your research.</p> <p style="text-align: center;"><i>Yvonne Lefebvre</i> _____ Dr. Yvonne Lefebvre Vice President Research and Academic Affairs Providence Health Care</p> <p>Date: <u>Jan 24 /06</u></p>			



**CHILDREN'S & WOMEN'S HEALTH
CENTRE OF BRITISH COLUMBIA**

Research Review Committee

January 03, 2007

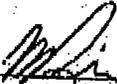
Room 202, 950 West 28th Avenue
Vancouver, BC V5Z 4H4
Phone: 604-875-3103/3194
Fax: 604-875-2498

Certificate of Approval -- Amendment --

PRINCIPAL INVESTIGATOR Skippen, Peter	Department Pediatrics	
CO-INVESTIGATORS: Christenson, Jim M.; Chute, William; Abu-Laban, Riyad; Pennington, Sarah; Andrusiak, Dug; Boychuk, Barb; Twaites, Brian;		
SPONSORING AGENCIES: National Institutes of Health; Canadian Institute for Advanced Research;		
CW DEPARTMENTS, PROGRAMS AND ADMINISTRATIVE JURISDICTIONS IMPACTED BY THIS STUDY Critical Care PBCU; Records Management; Radiology;		
PROJECT TITLE		
TERMS OF RENEWAL Jul 18 2006 - Jan 22 2007	AMENDMENT: Amendment 1 Summary, dd, January 2 2007. BC ROC In-Hospital Monitoring Plan, Version 1, January 2 2007. Hypertonic Resuscitation Following Traumatic Injury Protocol Amendment, October 29/06, dd, October 28 2006, Hospital Notice of Patient Enrollment, Ver 2, January 2 2007.	AMENDMENT APPROVED: 1/3/2007

CERTIFICATION:

The protocol for the above-named project has been reviewed by the Research Review Committee and has been found to be appropriate with respect to ethics, methodology, patient impact and availability of C&W resources


 Approval of the C&W Research Review Committee
 Dr. M. Levine, Chair
 Dr. M. Bond, Associate Chair

This Certificate of Approval is valid for the above term provided there is no change in the research protocol



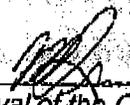
**CHILDREN'S & WOMEN'S HEALTH
CENTRE OF BRITISH COLUMBIA**

Research Review Committee

Room 202, 950 West 28th Avenue
Vancouver, BC V5Z 4H4
Phone: 604-875-3103/3194
Fax: 604-875-2496

July 18, 2006

Certificate of Approval

PRINCIPAL INVESTIGATOR Skippen, Peter	DEPARTMENT Surgery	NUMBER 06-0164
CO-INVESTIGATORS: Christenson, James; Chute, William; Abu-Laban, Riyad; Pennington, Sarah; Andrusiak, Dug; Boychuk, Barb; Twaites, Brian;		
C&W DEPARTMENTS, PROGRAMS AND ADMINISTRATIVE JURISDICTIONS IMPACTED BY THIS STUDY: Critical Care PBCU; Records Management; Radiology;		
SPONSORING AGENCIES: NIH, CIHR		
TITLE: Hyperbaric resuscitation following traumatic injury		
APPROVAL DATE July 18, 2006	TERM OF APPROVAL July 18, 2006 - January 22, 2007	
CERTIFICATION: The protocol for the above-named project has been reviewed by the Research Review Committee and has been found to be appropriate with respect to ethics, methodology, patient impact and availability of C&W resources  Approval of the C&W Research Review Committee Dr. M. Levine, Chair Dr. M. Bond, Associate Chair		
This Certificate of Approval is valid for the above term provided there is no change in the research protocol		

Vancouver Coastal Health
Research Institute
Healthier Lives through discovery



Bernard H. Bressler, PhD

Vice President, Research, Vancouver Coastal Health
 Executive Director, Vancouver Coastal Health Research Institute

Assistant Dean Research, Faculty of Medicine
 The University of British Columbia

February 5, 2007

Dr. Morad Hameed
 Trauma Services
 855 West 12th Avenue
 Vancouver, B.C.

Vancouver Coastal Health Authority Research Study #V06-0165

RENEWAL CERTIFICATE OF APPROVAL

TITLE: Hypertonic Resuscitation Following Traumatic Injury

SPONSOR: Canadian Institutes of Health Research; National Institutes of Health

This is to inform you that your project has been renewed for one year. Approval has been granted until January 22, 2008 based on the following:

1. UBC-Providence Ethics Committee Certificate of Renewal Approval – H05-50141
2. VCHA Request for Renewal Reply

Yours truly,

for:
 Dr. Bernard Bressler
 Vice-President Research

A joint venture in research between the Vancouver Coastal Health Authority and The University of British Columbia.
 Room 100 – 2647 Willow St., Vancouver, BC V5Z 3P1
 Tel: 604-875-5641, Fax: 604-875-5684
 www.vchri.ca



Bernard H. Bressler, PhD

Vice President, Research, Vancouver Coastal Health
 Executive Director, Vancouver Coastal Health Research Institute

Assistant Dean Research, Faculty of Medicine
 The University of British Columbia

July 10, 2006

Morad Hameed
 Trauma Services
 855 West 12th Avenue
 Vancouver, B.C.
 V5Z 1M9

Vancouver Coastal Health Authority Research Study #V06-0165

FINAL CERTIFICATE OF APPROVAL

TITLE: Hypertonic Resuscitation Following Traumatic Injury

Sponsor: Grant: NIHR & CIHR

This is to inform you that your project has been approved and can start immediately. Approval has been granted until **January 23, 2007** based on the following:

1. UBC/Providence Ethics Committee Certificate of Approval #P05-0141
2. VCHA Clinical Trials Administration Office Approval

Yours truly,


 Dr. Bernie Bressler
 Vice-President Research

A joint venture in research between the Vancouver Coastal Health Authority and The University of British Columbia.
 VGH Research Pavilion, 828 West 10th Avenue, Vancouver, BC V5Z 1L8
 Tel: 604-875-5641, Fax: 604-875-3684 www.vchri.ca



Better health. Best in health care.

Fraser Health
Research Ethics Board

FHA, Research Administration & Development
#300, 10334 152A Street, Surrey, BC V3R 7P8
Phone: 604.587.4436 Fax: 604.587.4665

**CERTIFICATE OF APPROVAL FOR AMENDMENT OF A PREVIOUSLY
APPROVED STUDY**

Official Notification - FHREB Number (to be used on all future correspondence): FHREB 2006-038	
Principal Investigator: Dr. Morad Hameed	Hospital/Facility & Department: St. Paul's Hospital, Emergency Room
Institution(s) or Geographical Areas where research will be carried out: Burnaby Hospital, Royal Columbian Hospital, Eagle Ridge Hospital, Ridge Meadows Hospital, MSA General Hospital, Chilliwack General Hospital, Fraser Canyon Hospital, Langley Memorial Hospital, Peace Arch Hospital, Surrey Memorial Hospital, and Delta Hospital	
Co-Investigator(s): Iain MacPhail, James Christenson, Riyad Abu-Laban, Dr. Bill Henderson	
Funding Agencies and/or Corporate Sponsor: U.S. National Institutes of Health Research, CIHR	
Title: Hypertonic Resuscitation Following Traumatic Injury	
Date of Approval of Amendment: 2007 January 31	Expiry Date of FHREB Approval: 2007 July 04 (This includes ALL previous amendments)
Term of approval is limited to the one year period of the initial approval or most recent annual renewal for this study.	Type of Approval: <input checked="" type="checkbox"/> Expedited <input type="checkbox"/> Full FHREB Review
Documents Included in this Approval: <ul style="list-style-type: none"> × Protocol Amendment No. 1 dated 2006 October 28 × Hospital Notification of Patient Enrollment - Version 2 dated 2007 January 2 × BC ROC In-Hospital Monitoring Plan for RCH HS Protocol Amendment Dated 2006 October 28 	

CERTIFICATION:

With respect to clinical trials:

1. The membership of the Fraser Health Research Ethics Board complies with the membership requirements for research ethics boards as defined in Division 5 of the Food and Drug Regulations and the Tri-Council Policy Statement.
2. The Fraser Health Research Ethics Board carries out its functions in a manner consistent with Good Clinical Practices.
3. The Fraser Health Research Ethics Board has reviewed and approved the clinical trial protocol and the informed consent form for the trial which is to be conducted by a qualified investigator named at the specified clinical trial site. This approval of the documentation listed above and the views of the Fraser Health Research Ethics Board have been documented in writing.

With respect to expedited review:

A co-chair of the FHREB has reviewed and approved the documentation listed above for the forenamed research study in accordance with the FHREB Policy on "Ethical Conduct of Research and Other Studies Involving Human Subject" and the Tri-council Policy Statement: Ethical Conduct for Research Involving Human".

With respect to full board review:

Full FHREB review and approval of the documentation listed above was completed for non-expedited review in accordance with the FHREB Policy on "Ethical Conduct of Research and Other Studies Involving Human Subjects" and the Tri-council Policy Statement: Ethical Conduct for Research Involving Human".

The FHREB approval for this study expires ONE year from the approval date of the FHREB certificate of initial approval or subsequent FHREB certificate of renewal. Researchers must submit a Request for Annual Renewal for ongoing research studies prior to the expiry date in order to receive annual re-approval.

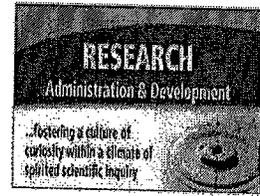
2007 January 31

APPROVAL OF THE FHREB BY ONE OF:
DR A BELZBERG or DR MR FOULKES
CO-CHAIRS, FHREB

DATE OF SIGNATURE



Better health.
Best in health care.



LETTER OF AUTHORIZATION TO BEGIN RESEARCH

July 5, 2006

Dr. Morad Hameed
Principal Investigator
St. Paul's Hospital
Emergency
1081 Burrard Street
Vancouver, BC
V6V 1Y6

Dear Dr. Hameed:

**RE: FHREB File #2006-038
Hypertonic Resuscitation Following Traumatic Injury**

The following required applicable approvals have been received and are in order:

FH REB Certificate of Initial Approval: **2006 July 04**

Consent Required and Approved

The signed signature page of the consent form for a specific study must be submitted to Health Records/Decision Support for the release of any personal information for that subject for that study. Ensure that the study title is included on the signature page of the consent form.

Consent Not Required [i.e. retrospective data analysis]

Consent Waiver

Department Agreement for Providing Research-related Services Authorization

Health Canada Letter of No Objection

Executed "Research Collaboration Agreement" dated 7th date of February 2006 and "Agreement" dated 29th day of May 2006

This letter authorizes the principal investigator to begin research-related procedures.

Please note that the ethical approval for this study must be renewed before the one year expiry date of the certificate of initial approval if the study will be ongoing at that time.

Yours Sincerely,

Susan Chunick,
Director, FH Research Administration & Development

Fraser Health Authority
Research Administration and
Development

#300-10334 152A St.
Surrey, BC
V3R 7P8

Tel (604) 587-4436
Fax (604) 587-4665

July 19, 2006

Dr. Morad Hameed MD MPH FRCSC
Assistant Professor of Surgery
University of British Columbia
Trauma Services, Vancouver General Hospital
855 West 12 Avenue
Vancouver, BC V5Z 1M9

Dear Dr. Hameed,

Re: "Hypertonic Resuscitation Following Traumatic Injury"

On behalf of the Richmond Health Services Delivery Area (RHSDA) Research Advisory Committee (RAC), I would like to thank you for submitting the above named research proposal.

The RAC reviewed the information you provided and has granted final approval for the study to proceed. The RAC would ask that you:

- Notify the RAC Secretary of the start date for research,
- Notify the committee of any changes to the study protocol following RAC approval,
- Provide 3 or 6 month progress reports for RAC information,
- Provide a copy of the final research report for RAC information and files.

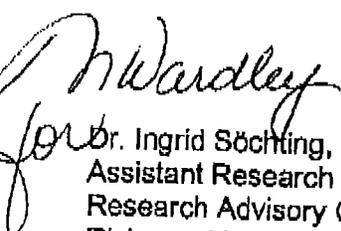
Submissions should be forwarded to:

Marion Wardley
C/o Quality Initiatives
Richmond Health Services
7000 Westminster Highway
Richmond, BC V6X 1A2

Fax. No.: 604-244-5292
Tel. No.: 604-244-5209

Thank you for providing the opportunity for RHS to participate in this study.

Yours sincerely,


for Dr. Ingrid Söchting,
Assistant Research Director
Research Advisory Committee
Richmond Health Services Delivery Area