

ROC Site Status & Enrollment as of 4/30/2007									
Milwaukee		IRB		Initial Approval	Approval to Start Study	FDA Amendment Approval	Shock Cohort Enrolled	TBI Cohort Enrolled	Community Consultation Completed
Overarching IRB-Medical College of Wisconsin Hospital							9	3	Jul-06
Children's Hospital of Wisconsin		Children's Hospital		7/12/2005	9/6/2006	12/5/2006			
Medical College of Wisconsin (no pts) oversees:		Medical College of Wisconsin		7/5/2005	7/24/2006	12/74/2006			
Froedtert Hospital		Medical College of Wisconsin		7/5/2005	7/24/2006	12/14/2006			
EMS Agency									
Milwaukee County EMS System*		Medical College of Wisconsin		7/5/2005	7/24/2006	12/14/2006			
*All agencies are enrolling subjects									

Shock Enrollment Breakdown as of 4/30/2007									
EMS Agencies/Hospitals		Children's Hospital	Froedtert Hospital	Died in the Field	Total				
Milwaukee County EMS System*		1	7	1	9				

TBI Enrollment Breakdown as of 4/30/2007									
EMS Agencies/Hospitals		Children's Hospital	Froedtert Hospital	Died in the Field	Total				
Milwaukee County EMS System*		0	3		3				



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*file
copy -
original
to Dave
Kitscha*

PO Box 1997
Milwaukee, WI 53201-1997
Phone (414) 266-2000
www.chw.org



**IRB APPROVAL
AMENDMENT**

December 5, 2006

Karen Brasel, MD
Tom Aufderheide, MD
Emergency Medicine
9200 West Wisconsin Avenue
Milwaukee, WI 53226

Dear Drs. Brasel and Aufderheide:

Administrative approval has been granted on behalf of the Human Research Review Board for the following amendment **Hypertonic Resuscitation Following Traumatic Injury** which was requested on November 29, 2006. This will be known as **Amendment IV**.

- **Addition of Closer monitoring and reporting to increase safety to subjects**
- **Dr. Winthrop added to the study as co-investigator.**

The following Protocol Numbers will remain unchanged: **CHW 05/89, FMLH: 05-070, HRRC 163-05.**

The Consent form approved **December 1, 2006** should be used from this date forward.

Any changes in the protocol and any severe untoward reactions must be reported in writing immediately to the Board. Changes in approved research, during the period for which Board approval has already been given, may not be initiated without Board review and approval except where necessary to eliminate apparent, immediate hazards to the human subjects.

When the above work is completed or discontinued, the Board must be notified in order to maintain an accurate record of all current projects.

Sincerely,

J. Paul Scott, MD, Chair
Human Research Review Board

cc: David Kitscha
Melanie Skorzewski



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**IRB APPROVAL
AMENDMENT**

September 15, 2006

Karen Brasel, MD
Tom Aufderheide, MD
FMCLB 294H

Dear Drs. Brasel and Aufderheide:

Please be advised that the amendment for your protocol entitled: **Hypertonic Resuscitation Following Traumatic Injury** was approved at the Human Research Review Board and Privacy Board Meeting on September 6, 2006 for Children's Hospital of Wisconsin. This will be known as Amendment II.

- Approval to conduct public notification and start the study.
- Review of hospital records on all subjects under the waiver of informed consent while the process of obtaining informed consent for continued participation is ongoing.
- Removal of listing the risks of pulmonary edema, osmotic demyelination, and decreased kidney function.
- Administrative / editorial changes to consent.
- Risks updated to include new information on Rituximab; additional serious viral infections and bowel obstruction / perforation.

The following Protocol Numbers will remain unchanged: CHW 05/89, HRRC 263-05

The Consent Form approved September 15, 2006 must be used from this date forward

Any changes in the protocol and any severe untoward reactions must be reported in writing immediately to the Board. Changes in approved research, during the period for which Board approval has already been given, may not be initiated without Board review and approval except where necessary to eliminate apparent, immediate hazards to the human subjects.

When the above work is completed or discontinued, the Board must be notified in order to maintain an accurate record of all current projects.

Sincerely,

J.P. Scott, MD, Chair
Human Research Review Board

cc: David Kitscha
Melanie Skorzewski



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IRB APPROVAL

July 12, 2005

Karen Brasel, MD
Tom Aufderheide, MD
FWC 294H

Dear Drs. Brasel and Aufderheide:

Please be advised that your protocol, entitled **Hypertonic Resuscitation Following Traumatic Injury** was approved at the Human Research Review Board (HRRB) and Privacy Board Meeting on **June 1, 2005** for Children's Hospital of Wisconsin (CHW).

For purposes of identification, this research has been assigned the following numbers: **CHW 05/89, HRRC 263-05**. *All CHW protocols are also registered with the Medical College of Wisconsin's Human Research Review Committee (HRRC) and are thus also assigned a registration number by the Medical College of Wisconsin's HRRC.*

The Consent and HIPAA Forms approved **July 8, 2005** must be used from this date forward

This protocol is approved for 1-year from the date of the Board meeting and a continuing review is scheduled for June 1, 2006. A Continuing Review Form will be forwarded three months prior to this review date. Failure to submit the Continuing Review Form in a timely manner may result in the termination of your research approval.

Any changes in the protocol, Consent Form or Assent Form, and any serious adverse reactions, or death, must be reported in writing immediately to the Children's Hospital of Wisconsin's HRRB at Mail Station #959 (phone number 414-266-2986).

Federal regulations require that if any advertising is involved in the initiation of this protocol, prior approval must be obtained from Children's Hospital's HRRB.

If this is a sponsored research project, it is incumbent upon the Principal Investigator to be aware of the Quality Assurance requirements of the sponsor and to carry out the project accordingly.

When the above work is completed or discontinued, the Board must be notified in order to maintain an accurate record of all current projects.

If you leave the staff of the hospital, you are expected to notify the Board in writing to whom the protocol should be transferred; otherwise, the protocol will be terminated.

Sincerely,

J.P. Scott, MD, Chair
Human Research Review Board

cc: Gail Radonski
• David Kitscha
Melanie Skorzewski



*Medical College of Wisconsin
Froedter Hospital
Institutional Review Board &
Human Research Review Committee*

EXPEDITED AMENDMENT APPROVAL NOTIFICATION

Date: December 14, 2006

To: Karen J. Brasel, MD
David Katscha
Department of Surgery

Re: Hypertonic Resuscitation following Traumatic Injury
EMLH # 05-070 HRR # 163-05

Changes have been made to the informed consent form to reflect the serum sodium monitoring. On page 3, we have added verbiage about the serum sodium draws in the "what has happened so far" section, and on page 5 we have added a bullet point to the risk section.

Expedited approval for the above-referenced amendment has been granted by the MCW/FH Committee #2. This approval is effective as of the date of this letter.

Research must be conducted according to the protocol that was approved by the IRB.

Any and all proposed changes to this submission (protocol form, consent documents, advertisements, questionnaires, etc) must be submitted to the IRB for review and approval prior to implementation.

All adverse events must be reported in accordance with the Medical College of Wisconsin IRB policies and procedures. When it is necessary to eliminate immediate hazards to participants, make changes as necessary first and then submit a protocol deviation form and amendment to the IRB.

If you have any questions regarding this letter, please contact your IRB Coordinator II, Mike Bingham, at 456-8464 or mbingham@mcw.edu.

Sincerely,

Ryan Spellacy, PhD
Chair, MCW/FH IRB Committee #2



*Medical College of Wisconsin
Froedert Hospital
Institutional Review Board &
Human Research Review Committee*

APPROVAL NOTIFICATION

Date: July 28, 2006

To: Karen Brasel, MD
Department of Surgery

Re: Hypertonic Resuscitation following Traumatic Injury
FMLH #05-070 HRR #163-05

IRB Approval Date: July 24, 2006

IRB Expiration Date: July 23, 2007

At the May 16, 2005 meeting, the MCW/FH IRB Committee #2 reviewed and conditionally approved this protocol pending the receipt of requested modifications, including the results of community consultation. The requested modifications have been submitted and reviewed, thus final approval is now being granted for this study for 12 months. The consent form is granted approval as of July 24, 2006 and must be used from this day forward. Public notification for this study may also commence.

The items below were submitted, reviewed, and approved by the IRB:

- Hypertonic Resuscitation following Traumatic Injury – Protocol Summary – Version 6, 6/23/06
- Hypertonic Resuscitation following Traumatic Injury – Informed Consent – Version 6, 6/23/06
- Hypertonic Resuscitation following Traumatic Injury – Appendices and Attachments
- Media Plan

The IRB approved consent document will contain an IRB approval stamp on each page. You must use the documents with the approval stamp for obtaining informed consent. Signed consent forms for each participant involved in this study must be kept on file as part of your study records.

This protocol met the waiver of Informed Consent in Emergency Research detailed in 21 CFR Section 50.24.

Research must be conducted according to the protocol that was approved by the IRB.

Any and all proposed changes to this submission (protocol form, consent documents, advertisements, questionnaires, etc) must be submitted to the IRB for review and approval prior to implementation.

In accordance with federal regulations, your next Continuing Progress Report must be reviewed prior to July 24, 2006. The Continuing Progress Report form must be received by the IRB with enough time to allow for review and approval prior to the expiration date. Failure to submit the Continuing Progress Report in a timely manner may result in the termination of IRB approval. Please notify the IRB within 30 days when all study activities and data analysis have been completed.

All adverse events must be reported in accordance with the Medical College of Wisconsin IRB policies and procedures. When it is necessary to eliminate immediate hazards to participants, make changes as necessary first and then submit a protocol deviation form and amendment to the IRB.



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If you wish to exclude members of the population who are under 18 years of age, please submit an amendment which updates the inclusion criteria, as well as a plan on how to assess if a participant is 18 years of age or older.

If you have any questions regarding this letter, please contact your IRB Coordinator II, Mike Bingham, at 456-8464 or mbingham@mcw.edu.

Sincerely,

Ryan Spellecy, PhD
Chair, MCW/FH IRB Committee #2.



*Medical College of Wisconsin
Froedert Hospital
Institutional Review Board &
Human Research Review Committee*

AMENDMENT APPROVAL NOTIFICATION

Date: July 28, 2006

To: Karen J. Brasel, MD
Department of Surgery

Re: Hypertonic Resuscitation following Traumatic Injury
FMLH #05-070 HRRC #163-05

Allow review of hospital records on all subjects under the waiver of informed consent while the process of obtaining informed consent for continued participation is ongoing.

Approval of the above-referenced amendment was granted by the MCW/FH IRB Committee #2 at the July 24, 2006 meeting.

Research must be conducted according to the protocol that was approved by the IRB.

Any and all proposed changes to this submission (protocol form, consent documents, advertisements, questionnaires, etc) must be submitted to the IRB for review and approval prior to implementation.

All adverse events must be reported in accordance with the Medical College of Wisconsin IRB policies and procedures. When it is necessary to eliminate immediate hazards to participants, make changes as necessary first and then submit a protocol deviation form and amendment to the IRB.

If you have any questions regarding this letter, please contact your IRB Representative, Mike Bingham, at 456-8464 or mbingham@mcw.edu.

Sincerely,

Ryan Spelleey, PhD
Chair, MCW/FH IRB Committee #2