

Snock Enrollment Breakdown as of 4/30/2007									
EMS Agencies/Hospitals									
	Baylor University Med Ctr	Methodist Dallas	Parkland Health	Died in the Field	Pre-Hosp Disposition Unknown	ED Unknown- No ED Admit Form	Total for Agency		
Care Flight (North Central Texas Services)*	1	2	3	0	0	0	0	0	6
Carrollton Fire Dept**	0	0	0	0	0	0	0	0	0
Dallas Fire Dispatch Center*	1	1	2	0	0	0	0	0	4
DeSoto Fire Dept**	0	0	0	0	0	0	0	0	0
Duncanville Fire Dept**	0	0	0	0	0	0	0	0	0
Garland Fire Dept**	0	0	0	0	0	0	0	0	0
City of Irving Fire Dept**	0	0	0	0	0	0	0	0	0
Lancaster Fire Dept**	0	0	0	0	0	0	0	0	0
Mesquite Fire Dept**	0	0	0	0	0	0	0	0	0
PHI Air*	0	0	1	0	0	0	0	0	1
Total for Hospital	2	3	6	0	0	0	0	0	11

TBI Enrollment Breakdown as of 4/30/2007									
EMS Agencies/Hospitals									
	Baylor University Med Ctr	Methodist Dallas	Parkland Health	Died in the Field	Pre-Hosp Disposition Unknown	ED Unknown- No ED Admit Form	Total for Agency		
Care Flight (North Central Texas Services)*	0	1	7	0	1	1	10		
Carrollton Fire Dept**	0	0		0	0	0	0		
Dallas Fire Dispatch Center*	2	0	0	0	0	0	2		
DeSoto Fire Dept**	0	0	0	0	0	0	0		
Duncanville Fire Dept**	0	0	0	0	0	0	0		
Garland Fire Dept**	0	0	0	0	0	0	0		
City of Irving Fire Dept**	0	0	0	0	0	0	0		
Lancaster Fire Dept**	0	0	0	0	0	0	0		
Mesquite Fire Dept**	0	0	0	0	0	0	0		
PHI Air*	0	0	1	0	0	0	1		
Total for Hospital	2	1	8	0	1	1	13		



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Suite 125
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IRB APPROVAL - Revisions to Previously Approved Projects

December 7, 2006

Michael A. E. Ramsay, MD
Anesthesiology
2nd Floor Roberts
3500 Gaston Avenue
Dallas, TX 75246

Re: Hypertonic Resuscitation Following Traumatic Injury

Project#: 006-154 Protocol#: N/A
Sponsor: NIH

Protocol Dt: 11/08/2005

The following items were reviewed at the 12/07/2006 meeting and approved:

- Research Protocol (11/08/2005)
FDA Letter (11/14/2006)
- Amendment - Other (10/28/2006; 1)
- Change in Study Staff - Dr. Michael Foreman (11/27/2006)
- IRB Form 7 - Revisions (11/27/2006)

The Institutional Review Board has reviewed the above referenced research project in accordance with 45 CFR 46, 21 CFR 50 & 56 and 45 CFR 164. This review was conducted at a meeting of the fully convened IRB.

The Board reminds you that Baylor Policy requires that that unless waived, fully documented informed consent must be obtained in accordance with 45 CFR 46.116 and 21 CFR 50.20 from all human subjects involved in this research study. Informed consent must be obtained by the principal investigator or other key personnel as listed in this submission. Documentation of informed consent must be kept on file for a period of three years past completion or discontinuation of the study and will no doubt be subject to inspection in the future.

In addition, 45 CFR 164 requires that, unless waived by the IRB, authorization must be obtained for use and disclosure of Protected Health Information. If this project is currently open to new enrollment, the approved version of the consent form(s) is listed above. The document(s) reviewed in this submission has been determined to satisfy the requirements as outlined in 45 CFR 164.508.

Page 1 of 2

DHHS and FDA regulations require you to submit periodic and terminal progress reports to Baylor's Institutional Review Board and to receive at least annual approval of your activity from this Committee.

You are also required to report to this Committee immediately any death, unanticipated problems involving risks to subjects or others, or serious adverse incidents resulting from your study. These events must be reported in accordance with current BIRI Policies 830 and 838.

Federal regulations and institutional policies require that the IRB review any and all changes in your research activity. This includes amendments, revisions, administrative changes, advertisements, or ANY other change in the information as presented at initial review. In other words, should your project change, another review by the Board is required. Failure to comply with any of the above requirements, federal regulations, or institutional policy may result in severe sanctions being placed on the Medical Center and on you as the Principal Investigator. These sanctions could result in your research being permanently terminated for non-compliance.

Receipt of approval does not convey institutional authority to gain additional patient information. It is your responsibility as Principal Investigator to abide by institutional and/or departmental policies regarding confidentiality, access, and release of patient data.

Please be advised: there may be additional administrative requirements from Baylor Research Institute that must be met before the study may begin enrolling subjects.

Sincerely,



Lawrence R. Schiller, MD, Chair
Institutional Review Board - Blue

Project# 006-154

Page 2 of 2



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IRB APPROVAL

August 14, 2006

Michael A. E. Ramsay, MD
Anesthesiology
2nd Floor Roberts
3500 Gaston Avenue
Dallas, TX 75246

Re: Hypertonic Resuscitation Following Traumatic Injury

Project#: 006-154 Protocol#: N/A

Sponsor: NIH

Protocol Dt: 11/08/2005

The following items were reviewed at the 08/03/2006 meeting and approved, pending minor modifications in each item marked with an asterisk (*):

- Research Protocol (11/08/2005)
- FDA Approval Letter (02/16/2006)
- Community Consultation Plan
- * Consent Form - Shock (07/24/2006)
- * Consent Form - TBI (07/24/2006)
- Education Report (07/11/2006)
- * IRB Form 1 - Application and Project Summary (07/24/2006)
- IRB Form 18 - Review of Scientific and Scholarly V (07/10/2006)
- IRB Form 23-Authorization to Enroll Children in Re (07/10/2006)
- * Notification Letter to Subject - English & Spanish - A (07/10/2006)
- * Notification Letter to Subject - English & Spanish - B (07/10/2006)
- Spanish Short Form (07/24/2006)

Consent Form - Shock (07/24/2006) was returned to you requiring minor modifications. The following revised items incorporate those modifications and are now approved:

- Consent Form - Shock (08/09/2006)

Consent Form - TBI (07/24/2006) was returned to you requiring minor modifications. The following revised items incorporate those modifications and are now approved:

- Consent Form - TBI (08/09/2006)

IRB Form 1 - Application and Project Summary (07/24/2006) was returned to you requiring minor modifications. The following revised items incorporate those modifications and are now approved:

- IRB Form 1 - Application and Project Summary (08/09/2006)

Notification Letter to Subject - English & Spanish - A (07/10/2006) was returned to you requiring minor modifications. The following revised items incorporate those modifications and are now approved:

- Notification Letter to Subject - English & Spanish - A (08/09/2006)

Notification Letter to Subject - English & Spanish - B (07/10/2006) was returned to you requiring minor modifications. The following revised items incorporate those modifications and are now approved:

- Notification Letter to Subject - English & Spanish - B (08/09/2006)

Approval is granted for a period not to exceed 12 months and will expire on 08/02/2007. Your Continuing Review is scheduled for 07/05/2007.

The Institutional Review Board has reviewed the above referenced research project in accordance with 45 CFR 46, 21 CFR 50 & 56 and 45 CFR 164. This review was conducted at a meeting of the fully convened IRB.

The Board reminds you that Baylor Policy requires that that unless waived, fully documented informed consent must be obtained in accordance with 45 CFR 46.116 and 21 CFR 50.20 from all human subjects involved in this research study. Informed consent must be obtained by the principal investigator or other key personnel as listed in this submission. Documentation of informed consent must be kept on file for a period of three years past completion or discontinuation of the study and will no doubt be subject to inspection in the future.

In addition, 45 CFR 164 requires that, unless waived by the IRB, authorization must be obtained for use and disclosure of Protected Health Information. If this project is currently open to new enrollment, the approved version of the consent form(s) is listed above. The document(s) reviewed in this submission has been determined to satisfy the requirements as outlined in 45 CFR 164.508.

DHHS and FDA regulations require you to submit periodic and terminal progress reports to Baylor's Institutional Review Board and to receive at least annual approval of your activity from this Committee.

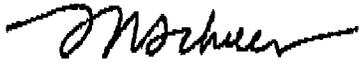
You are also required to report to this Committee immediately any death, unanticipated problems involving risks to subjects or others, or serious adverse incidents resulting from your study. These events must be reported in accordance with current BIRI Policies 830 and 838.

Federal regulations and institutional policies require that the IRB review any and all changes in your research activity. This includes amendments, revisions, administrative changes, advertisements, or ANY other change in the information as presented at initial review. In other words, should your project change, another review by the Board is required. Failure to comply with any of the above requirements, federal regulations, or institutional policy may result in severe sanctions being placed on the Medical Center and on you as the Principal Investigator. These sanctions could result in your research being permanently terminated for non-compliance.

Receipt of approval does not convey institutional authority to gain additional patient information. It is your responsibility as Principal Investigator to abide by institutional and/or departmental policies regarding confidentiality, access, and release of patient data.

Please be advised: there may be additional administrative requirements from Baylor Research Institute that must be met before the study may begin enrolling subjects.

Sincerely,



Lawrence R. Schiller, MD, Chair
Institutional Review Board ~ Blue



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IRB APPROVAL PENDING MODIFICATIONS

August 3, 2006

Michael A. E. Ramsay, MD
Anesthesiology
2nd Floor Roberts
3500 Gaston Avenue
Dallas, TX 75246

Re: Hypertonic Resuscitation Following Traumatic Injury

Project#: 006-154 Protocol#: N/A

Sponsor: NIH

Protocol Dt: 11/08/2005

The following items were reviewed at the 08/03/2006 meeting and approved, pending minor modifications in each item marked with an asterisk (*):

- Research Protocol (11/08/2005)
- FDA Approval Letter (02/16/2006)
- Community Consultation Plan
- * Consent Form - Shock (07/24/2006)
- * Consent Form - TBI (07/24/2006)
- Education Report (07/11/2006)
- IRB Form 1 - Application and Project Summary (07/24/2006)
- IRB Form 18 - Review of Scientific and Scholarly V (07/10/2006)
- IRB Form 23-Authorization to Enroll Children in Re (07/10/2006)
- * Notification Letter to Subject - English & Spanish - B (07/10/2006)
- * Notification Letter to Subject - English & Spanish A (07/10/2006)
- Spanish Short Form (07/24/2006)

Contingent Approval - Revised Item(s) Due: 09/17/2006

IRB FORM 1

Number 17 - Should be changed to indicate use of Spanish Short Form version that is supplied.

CONSENT FORMS**WHAT IF I AM INJURED OR BECOME ILL WHILE PARTICIPATING IN THIS STUDY?**

Shock Consent - strike orphan bullet at top of page 5 of 7.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Shock and TBI Consents - The first sentence should be changed to read "Continuing to take part in this study is voluntary."

CONFIRMATION OF CONSENT

Shock Consent - Page 7 of 7 and TBI Consent, page 7 of 7 - Each should include additional line for signature of guardian of patients 15-17 years old. Add line at the end of document as follows: Signature of parent or guardian if applicable (required for subjects 15-17 years of age). Also include a line for date and time.

OTHER

Notification Letter A - English - 2nd paragraph, last line should be changed to, "of his/her injury".

Notification Letter B - English - 2nd paragraph, last sentence, should be changed to, "Due to the severity of his/her injury".

The Board has stipulated that the above outlined specific modifications be made prior to granting final approval. Upon satisfaction of these stipulations, further review is required by a representative of the IRB prior to beginning the research.

Once the requested changes are made, please submit three copies of the revised documents with the revision date (e.g. Revised _____) typed at the top right hand corner of the document. One copy, for our files, needs to have the changes highlighted in yellow. Since the revision date should be changed, this should be highlighted on this copy as well. The copy which does not have changes highlighted, when approved, will be returned to you stamped with the approval period.

Revised documents must be submitted prior to the expiration date listed above. Documents received after this date will need to be resubmitted as a new study.

In order to assist us in confirming that all changes have been made, please include a copy of this letter with your corrected submission.

In addition, if this is a sponsored study please remember that a signed contract must be on file in the Baylor Research Institute before research can commence.

Sincerely,



Lawrence R. Schiller, MD, Chair
Institutional Review Board ~ Blue



P.O. Box 659999
Dallas, Texas 75265-6999
1441 N. Beckley Ave.
Dallas, Texas 75203
214.947.6181

December 22, 2006

**Hypertonic Resuscitation Following Traumatic Injury
Modifications**

Sponsor: NIH

IND: Traumatic Brain Injury IND#12505

IND: Hypovolemic Shock IND#12506

PI: Robert Simonson, DO

Sub-Investigator(s): Ahamed H. Idris, MD, Dixie L. Climer, RN, Melinda Moffat, RN.

Re: Protocol Amendment #1 Dated (10/28/06), Revised 1572 dated 11/10/06

IRB No. 2006.00.376.A

Your above study protocol amendment (10/24/06) was reviewed and approved on December 13, 2006 during its initial review, along with the investigators listed in the application (yourself, Dra. Idris, Mangram, Climer & Moffat).

Action Item required within 30 days:

During the meeting the board reviewed and discussed a discrepancy in your protocol (pages 13 & 14 - Table 2) dated 11/08/05. Table #2 on page 14 does not match the data that is listed on page 13. Please send a letter to the IRB board within 30 days addressing and clarifying the discrepancy for the above captioned items.

Once the protocol revisions and issues are completed please send to the IRB for review and approval.

Once the requested changes are made if any, please submit three copies of the revised above documents with the revision date (e.g. revised _____) typed at the top right hand corner of the document. One copy, for our files, needs to have the changes highlighted in yellow. Since the revision data should be changed, this should be highlighted on this copy as well. The copy which does not have changes highlighted, when approved, will be returned to you stamped with the approval period.

Confidentiality in the use of data requires at a minimum: (a) not abstracting personal identifiers such as names, addresses, telephone numbers, e-mail addresses, or Social Security Numbers except when essential to an approved study protocol; (b) removing coded personal identifiers such as clinic or hospital numbers at the earliest stage of the research compatible with the study goals, such as after linking data from various sources together; (c) if coded personal identifiers must remain to combine with future data, these should be encrypted and not be the plain clinic or hospital numbers; and (d) the data files should be kept in a secure environment such as a locked cabinet or a properly secured computer file with password protection.

The next continuing review is due on or before August 9, 2007. Please send your continuing review form to the IRB office at least 21 days before your study expires.

The approval decision for the study is based on minimizing risk, acceptable risk-benefit ratio for subjects, equitable selection of subjects, confidentiality in the use of data¹ and properly executed and documented informed consent.

Vulnerable Population: The Board has found that some or all of the subjects are vulnerable to coercion or undue influence by virtue of their disease, chronic condition. Accordingly, the Board expects that extra care will be taken in the consent process to avoid any coercion or undue influence to participate in this research study.

You must fulfill all requirements of the IRB written procedures including but not limited to the following:

1. Conduct the research as required by the Protocol.
2. Use only the Consent Form approved by the Board.
3. If you provide Non-English speaking patients with a translation of the approved Consent Form in the patient's first language it must be certified and approved by the IRB. The Board must approve the translated version.
4. Obtain pre-approval from the Board of any changes in the research activity (except when necessary to protect human subjects (HHS 45 CFR & 46.103(b)(4); FDA 21 CFR & 56.108(a)(3)); immediately report to the Board any such emergency changes for the protection of human subjects.
5. Within 5 days, report in writing to the Board the death, hospitalization, or serious illness of any study subject enrolled in a Methodist IRB approved protocol that is or may be related to your study.
6. Within (5) days, promptly report to the Board any new information that might adversely affect the safety of the subjects or the conduct of the trial.
7. Provide reports to the Board concerning the progress of the research, when requested.
8. Obtain pre-approval of study advertisements from the Board before use.
9. Conduct the informed consent process, without coercion or undue influence and provide the potential subject sufficient opportunity to consider whether or not to participate.

Confidentiality in the use of data requires at a minimum: (a) not abstracting personal identifiers such as names, addresses, telephone numbers, e-mail addresses, or Social Security Numbers except when essential to an approved study protocol; (b) removing coded personal identifiers such as clinic or hospital numbers at the earliest stage of the research compatible with the study goals, such as after linking data from various sources together; (c) if coded personal identifiers must remain to combine with future data, these should be encrypted and not be the plain clinic or hospital numbers; and (d) the data files should be kept in a secure environment such as a locked cabinet or a properly secured computer file with password protection.

In order to assist us in confirming that all changes have been made, please include a copy of this letter with your corrected submission.

The next continuing review is due on or before August 9, 2007. Please send your continuing review form to the IRB office at least 21 days before your study expires.

The approval decision for the study is based on minimizing risk, acceptable risk-benefit ratio for subjects, equitable selection of subjects, confidentiality in the use of data¹ and properly executed and documented informed consent.

Vulnerable Population: The Board has found that some or all of the subjects are vulnerable to coercion or undue influence by virtue of their disease, chronic condition. Accordingly, the Board expects that extra care will be taken in the consent process to avoid any coercion or undue influence to participate in this research study.

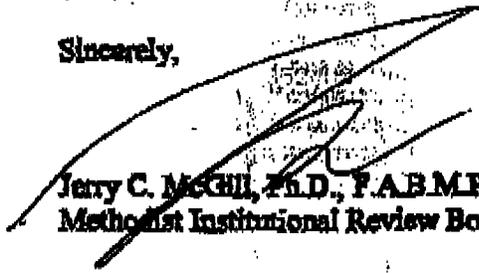
You must fulfill all requirements of the IRB written procedures including but not limited to the following:

1. Conduct the research as required by the Protocol.
2. Use only the Consent Form approved by the Board.
3. If you provide Non-English speaking patients with a translation of the approved Consent Form in the patient's first language it must be certified and approved by the IRB. The Board must approve the translated version.
4. Obtain pre-approval from the Board of any changes in the research activity (except when necessary to protect human subjects ;(HHS 45 CFR & 46.103(b)(4); FDA 21 CFR & 312.61(a)(3)); immediately report to the Board any such emergency changes for the protection of human subjects.
5. Within 5 days, report in writing to the Board the death, hospitalization, or serious illness of any study subject enrolled in a Methodist IRB approved protocol that is or may be related to your study.
6. Within (5) days, promptly report to the Board any new information that might adversely affect the safety of the subjects or the conduct of the trial.
7. Provide reports to the Board concerning the progress of the research, when requested.
8. Obtain pre-approval of study advertisements from the Board before use.
9. Conduct the informed consent process, without coercion or undue influence and provide the potential subject sufficient opportunity to consider whether or not to participate.

Confidentiality in the use of data requires at a minimum: (a) not abstracting personal identifiers such as names, addresses, telephone numbers, e-mail addresses, or Social Security Numbers except when essential to an approved study protocol; (b) removing coded personal identifiers such as clinic or hospital numbers at the earliest stage of the research compatible with the study goals, such as after linking data from various sources together; (c) if coded personal identifiers must remain to combine with future data, these should be encrypted and not be the plain clinic or hospital numbers; and (d) the data files should be kept in a secure environment such as a locked cabinet or a properly secured computer file with password protection.

If you have any questions or need additional information please contact the IRB office at (214) 947-2542.

Sincerely,



Jerry C. McMillan, Ph.D., F.A.B.M.P.
Methodist Institutional Review Board Chairman

Confidentiality in the use of data requires at a minimum: (a) not abstracting personal identifiers such as names, addresses, telephone numbers, e-mail addresses, or Social Security Numbers except when essential to an approved study protocol; (b) removing coded personal identifiers such as clinic or hospital numbers at the earliest stage of the research compatible with the study goals, such as after linking data from various sources together; (c) if coded personal identifiers must remain to combine with future data, these should be encrypted and not be the plain clinic or hospital numbers; and (d) the data files should be kept in a secure environment such as a locked cabinet or a properly secured computer file with password protection.

SEP. 25. 2006 11:33AM

MMC ADMIN



P.O. Box 655999
Dallas, Texas 75265-5999
1441 N. Beckley Ave.
Dallas, Texas 75209
214-647-8181

September 22, 2006

Hypertonic Resuscitation Following Traumatic Injury

Sponsor: NIH

IND: Traumatic Brain Injury IND#12505

IND: Hypovolemic Shock IND#12506

PI: Robert Simonson, DO

Sub-Investigator(s): Ahmed H. Idris, MD, Dicie L. Climer, RN, Melinda Moffat, RN.

IRB No. 2006.00.376.A

Re: Revised *Trauma Notification Letter to Subject (English & Spanish)

*Shock Notification Letter to Subject (English & Spanish)

Version Date: 09/07/06

Revised *Informed Consents: (English & Spanish) Trauma & Shock

Version Date: 09/07/06

Your above study protocol revised documents were reviewed and approved on September 22, 2006 by expedited review, along with the investigators listed in the application (yourself, Dra. Idris, Climer & Moffat) for a period of 1 year. Your approved number of subjects is 700. If during the course of your study if you feel you need to increase this number, please submit an amendment to the IRB for review and approval.

In addition, if this is a sponsored study please remember that a signed contract must be reviewed by Legal and Administration/VP, before research can commence.

The next continuing review is due on or before August 9, 2007. Please send your continuing review form to the IRB office at least 31 days before your study expires.

The approval decision for the study is based on minimizing risk, acceptable risk-benefit ratio for subjects, equitable selection of subjects, confidentiality in the use of data, and properly executed and documented informed consent.

Vulnerable Population: The Board has found that some or all of the subjects are vulnerable to coercion or undue influence by virtue of their disease, chronic condition.

Confidentiality in the use of data requires at a minimum: (a) not abstracting personal identifiers such as names, addresses, telephone numbers, e-mail addresses, or Social Security Numbers except when essential to an approved study protocol; (b) removing coded personal identifiers such as clinic or hospital numbers at the earliest stage of the research compatible with the study goals, such as after linking data from various sources together; (c) If coded personal identifiers must remain to combine with future data, these should be encrypted and not be the plain clinic or hospital number; and (d) the data files should be kept in a secure environment such as a locked cabinet or a properly secured computer file with password protection.

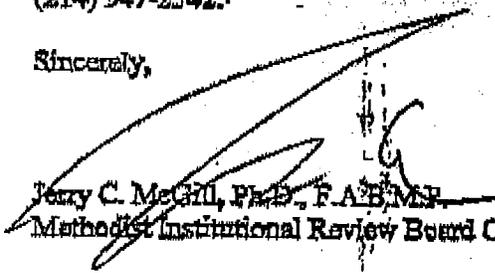
Accordingly, the Board expects that extra care will be taken in the consent process to avoid any coercion or undue influence to participate in this research study.

You must fulfill all requirements of the IRB written procedures including but not limited to the following:

1. Conduct the research as required by the Protocol.
2. Use only the Consent Form approved by the Board.
3. If you provide Non-English speaking patients with a translation of the approved Consent Form in the patient's first language it must certified and be approved by the IRB. The Board must approve the translated version.
4. Obtain pre-approval from the Board of any changes in the research activity (except when necessary to protect human subjects (HHS 45 CFR & 46.103(b)(4); FDA 21 CFR & 316.108(a)(3)); immediately report to the Board any such emergency changes for the protection of human subjects.
5. Within 5 days, report in writing to the Board the death, hospitalization, or serious illness of any study subject enrolled in a Methodist IRB approved protocol that is or may be related to your study.
6. Within (5) days, promptly report to the Board any new information that might adversely affect the safety of the subjects or the conduct of the trial.
7. Provide reports to the Board concerning the progress of the research, when requested.
8. Obtain pre-approval of study advertisements from the Board before use.
9. Conduct the informed consent process, without coercion or undue influence and provide the potential subject sufficient opportunity to consider whether or not to participate.

If you have any questions or need additional information please contact the IRB office at (214) 947-2542.

Sincerely,


Terry C. McGill, Ph.D., F.A.B.M.P.
Methodist Institutional Review Board Chairman

Confidentiality in the use of data requires at a minimum: (a) not abstracting personal identifiers such as names, addresses, telephone numbers, e-mail addresses, or Social Security Numbers except when essential to an approved study protocol; (b) removing coded personal identifiers such as clinic or hospital numbers at the earliest stage of the research compatible with the study goals, such as after linking data from various sources together; (c) If coded personal identifiers must remain to combine with future data, these should be encrypted and not be the plain clinic or hospital numbers; and (d) the data files should be kept in a secure environment such as a locked cabinet or a properly secured computer file with password protection.

August 29, 2006

Re: Hypertonic Resuscitation Following Traumatic Injury * IRB Approval Pending
Modifications

Sponsor: NIH

IND: Traumatic Brain Injury IND#12505

IND: Hypovolemic Shock IND#12506

PI: Robert Simonson, DO

Sub-Investigator(s): Ahamed H. Idris, MD, Dixie L. Climer, RN, Melinda Moffat, RN.
IRB No. 2006.00.376.A

Your above study protocol (11/08/05) was reviewed and approved on August 09, 2006 during its initial review, along with the investigators listed in the application (yourself, Drs. Idris, Climer & Moffat) for a period of 1 year contingent on changes with the inclusive study documents*. **Your approved number of subjects is 700.** If during the course of your study if you feel you need to increase this number, please submit an amendment to the IRB for review and approval.

The following items were reviewed and approved:

- Research Protocol (11/08/2005)
- FDA Approval Letter (02/16/2006)
- Community Consultation Plan (DARP)

***Trauma** Notification Letter to Subject (English & Spanish)

***Shock** Notification Letter to Subject (English & Spanish)

*The Board stipulated that the Trauma and Shock Notification Letters to Subject be revised with the following changes:

- Revised and add a clearer description as to where the letters are coming from.
- Please delete the first 3 sentences of both letters because the treatment related to the study will actually take place prior to arriving to Methodist.

1

Confidentiality in the use of data requires at a minimum: (a) not abstracting personal identifiers such as names, addresses, telephone numbers, e-mail addresses, or Social Security Numbers except when essential to an approved study protocol; (b) removing coded personal identifiers such as clinic or hospital numbers at the earliest stage of the research compatible with the study goals, such as after linking data from various sources together; (c) If coded personal identifiers much remain to combine with future data, these should be encrypted and not be the plain clinic or hospital numbers; and (d) the data files should be kept in a secure environment such as a locked cabinet or a properly secured computer file with password protection.

- Please revise the second paragraph so that it relates to the treatment related to the study.
- Delete the name "Dixie Climer" and replace with the PI, Dr. Simonson, at the closing letter.

***Informed Consents:**
(English & Spanish)
Trauma & Shock:

The Board stipulated that the Trauma and Shock consent forms be revised with the following changes:

- Page 2: under section titled "Purpose" please delete the last sentence in the 2nd paragraph "The Institutional Review Board at the University of Texas Southwestern Medical Center oversees the safety of subjects in medical research and replace with Methodist Health System Institutional Review Board.
- Page 3: under section titled "Risks" 3rd paragraph: Please revise this sentence to include "You may or may not benefit from this research".
- Page 6: under section titled "What if I decide not to give my permission to use and give out my health information. Please change the "t" to "to".
- Page 7: under section titled "Question" please add a phone number for the IRB contact Phyllis Everage (214) 947-2542.

Once the consent form revisions and issues are completed the consent form can be reviewed and approved by the expedited review procedure.

Once the requested changes are made, please submit three copies of the revised above documents with the revision date (e.g. revised _____) typed at the top right hand corner of the document. One copy, for our files, needs to have the changes highlighted in yellow. Since the revision data should be changed, this should be highlighted on this copy as well. The copy which does not have changes highlighted, when approved, will be returned to you stamped with the approval period.

In order to assist us in confirming that all changes have been made, please include a copy of this letter with your corrected submission.

In addition, if this is a sponsored study please remember that a signed contract must be reviewed by Legal and Administration/VP, before research can commence.

The next continuing review is due on or before **August 9, 2007**. **Please send your continuing review form to the IRB office at least 21 days before your study expires.**

1

Confidentiality in the use of data requires at a minimum: (a) not abstracting personal identifiers such as names, addresses, telephone numbers, e-mail addresses, or Social Security Numbers except when essential to an approved study protocol; (b) removing coded personal identifiers such as clinic or hospital numbers at the earliest stage of the research compatible with the study goals, such as after linking data from various sources together; (c) If coded personal identifiers must remain to combine with future data, these should be encrypted and not be the plain clinic or hospital numbers; and (d) the data files should be kept in a secure environment such as a locked cabinet or a properly secured computer file with password protection.

The approval decision for the study is based on minimizing risk, acceptable risk-benefit ratio for subjects, equitable selection of subjects, confidentiality in the use of data¹ and properly executed and documented informed consent.

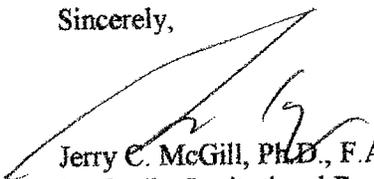
Vulnerable Population: The Board has found that some or all of the subjects are vulnerable to coercion or undue influence by virtue of their disease, chronic condition. Accordingly, the Board expects that extra care will be taken in the consent process to avoid any coercion or undue influence to participate in this research study.

You must fulfill all requirements of the IRB written procedures including but not limited to the following:

1. Conduct the research as required by the Protocol.
2. Use only the Consent Form approved by the Board.
3. If you provide Non-English speaking patients with a translation of the approved Consent Form in the patient's first language it must be certified and approved by the IRB. The Board must approve the translated version.
4. Obtain pre-approval from the Board of any changes in the research activity (except when necessary to protect human subjects ;(HHS 45 CFR & 46.103(b)(4); FDA 21 CFR & 56.108(a)(3)); immediately report to the Board any such emergency changes for the protection of human subjects.
5. Within 5 days, report in writing to the Board the death, hospitalization, or serious illness of any study subject enrolled in a Methodist IRB approved protocol that is or may be related to your study.
6. Within (5) days, promptly report to the Board any new information that might adversely affect the safety of the subjects or the conduct of the trial.
7. Provide reports to the Board concerning the progress of the research, when requested.
8. Obtain pre-approval of study advertisements from the Board before use.
9. Conduct the informed consent process, without coercion or undue influence and provide the potential subject sufficient opportunity to consider whether or not to participate.

If you have any questions or need additional information please contact the IRB office at (214) 947-2542.

Sincerely,



Jerry C. McGill, Ph.D., F.A.B.M.P.
Methodist Institutional Review Board Chairman

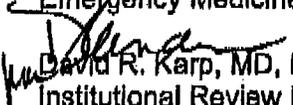
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Confidentiality in the use of data requires at a minimum: (a) not abstracting personal identifiers such as names, addresses, telephone numbers, e-mail addresses, or Social Security Numbers except when essential to an approved study protocol; (b) removing coded personal identifiers such as clinic or hospital numbers at the earliest stage of the research compatible with the study goals, such as after linking data from various sources together; (c) If coded personal identifiers must remain to combine with future data, these should be encrypted and not be the plain clinic or hospital numbers; and (d) the data files should be kept in a secure environment such as a locked cabinet or a properly secured computer file with password protection.

**UT SOUTHWESTERN
MEDICAL CENTER**

Institutional Review Board

TO: Ahamed H. Idris, MD
c/o Dixie L. Climer
Emergency Medicine/Surgery - MC #8579

FROM:  David R. Karp, MD, PhD
Institutional Review Board 1 Chairperson
IRB - 8843

DATE: February 26, 2007

RE: **Continuing Approval of the Protocol, CR Form, Progress Report, Project Summary, and Consent Form(s).**
IRB Number: 032006-028
Title: Hypertonic Resuscitation Following Traumatic Injury

Having met the conditions as set forth by the IRB at the February 19, 2007 meeting, your research protocol is now approved for continuation for a period of 12 months. This approval period will begin February 26, 2007 and last until February 18, 2008. If the research continues beyond approval period, the study will require continuing review from the IRB and a reminder will be mailed to you 60 days prior to the expiration date of stated above.

Please Carefully Read Important Compliance Information Below:

All subjects must sign a copy of the attached IRB-approved and stamped consent form(s) and HIPAA Authorization, if applicable, before undergoing any study procedures, including screening procedures that would not otherwise be performed for a patient/subject's medical condition in a non-research context.

The above referenced study is approved to enroll Spanish-speaking subjects. DHHS regulations permit oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally. A witness to the oral presentation is required, and the subject must be given copies of the short form document and the summary.

When this procedure is used with subjects who do not speak or read English, (1) the oral presentation and the short form written document should be in a language understandable to the subject; (2) the IRB-approved English language informed consent document may serve as the summary; and (3) the witness should be fluent in both English and the language of the subject.

At the time of consent, (1) the short form document should be signed by the subject (or the subject's legally authorized representative); (2) the summary (i.e., the English language informed consent document) should be signed by the person obtaining consent as authorized under the protocol; and (3) the short form document and the summary should be signed by the witness. When the person obtaining consent is assisted by a translator, the translator may

Page 2 of 3

serve as the witness.

For research involving therapeutic or prophylactic interventions or invasive diagnostic procedures, a bilingual translator must be continuously available to facilitate communications between research personnel and a subject. If a bilingual translator will not always be available, it may be unsafe for an otherwise eligible candidate to participate in the research if that person does not speak and read English.

Important Note: You must use a photocopy of the attached IRB-stamped consent form(s). Use of a copy of any consent form on which the IRB- stamped approval and expiration dates are replaced by typescript or handwriting is prohibited.

A photocopy of the signed consent form(s) and HIPAA Authorization should be given to each participant. The copy of the consent form(s) bearing original signatures should be kept with other records of this research for at least five years past the completion of the study. For research involving treatment or invasive procedures, a photocopy of the signed consent form(s) should be on file in a subject's medical record.

The Department of Health and Human Services (DHHS) regulations for the protection of human subjects require that informed consent information be presented in a language understandable to the subject(s), and, in most situations, that informed consent be documented in writing.

Where informed consent is documented, the written consent document(s) should embody, in language understandable to the subject, all of the elements necessary for legally effective informed consent. Potential subjects who do not speak or read English should be presented with a consent document written in a language understandable to them. The Office for Human Research Protections (OHRP) strongly encourages the use of this procedure whenever possible.

In the future, should you require a change or need to modify the research, including the informed consent document(s) and HIPAA Authorization, per federal regulation you must obtain prospective review and approval of the Institutional Review Board. For any change to the research, prior review and approval before implementing such changes is mandatory except when prompt implementation is necessary to eliminate apparent immediate hazard to a subject.

Approval by the appropriate authority at a collaborating facility is required before subjects may be enrolled on this study.

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If you have any questions related to this approval or IRB policies and procedures, you may telephone Denise Landers 214-648-2137.

Attachments: CR Form
Progress Report
Project Summary
Consent Form(s)

DK/dl

The University of Texas Southwestern Medical Center at Dallas

REC-01
11/20/06

IRB Form MOD

Request for Protocol/Consent Modifications
(revised February 2005)

File Number: 032006-028

Title of Research: Hypertonic Resuscitation Following Traumatic Injury

Principal Investigator (name printed): Ahamed H. Idris, MD

Department: Emergency Medicine
Surgery

Mall Code at UT Southwestern: 8579

Phone Number: 214-749-9054

Research Coordinator (name printed): Dixie L. Gilmer, RN

Mall Code at UT Southwestern: 8579

Phone Number: 214-648-0408

Directions: Per requirements of 45 CFR 46.103(b)(4) and 21 CFR 56.108(a)(3)(4), changes in approved research cannot be initiated without IRB review and approval unless necessary to eliminate apparent immediate hazards to the subject or provide important information germane to informed consent. In this circumstance, the IRB must be notified immediately. To review your Request for Protocol/Consent Modifications, the IRB must have the following information provided according to the specific instructions in each subpart. Additional pages can be used as necessary. The information should be typed.

Section I - Changes in Protocol

yes
 no

A) Description:

Describe each proposed change in the protocol separately in numbered sequence. If the proposed change will directly affect the subjects (e.g., additional tests, changes in drug dose or schedule, change in eligibility criteria, etc.), the justification/rationale for the change must be included. The investigator must advise the IRB in this section whether or not each proposed change that directly affects the subject requires revision of the consent document(s). Please submit (1) the previously approved protocol/project summary with **deletions red-lined**, (2) the proposed protocol/project summary with **additions highlighted**, and (3) a **fresh copy** of the new protocol/project summary. **The redlined and highlighted versions may be combined. Note: Section IB must be completed and copies of the revised consent form(s) must be submitted.**

Attached is the protocol and protocol amendment for Hypertonic Resuscitation Following Traumatic Injury. No changes have been made to the original study protocol. The protocol amendment outlines and explains the FDA approved changes.

The changes are related to increased monitoring and assessment of enrolled patients after hospital admission and potential variation in hospital treatment after admission. There are no changes to the study treatment protocol or to the consent form.

An information sheet about hypernatremia will be given to hospital personnel by the transferring EMS

3) BIOTEL will notify the Study Coordinator or investigator immediately when a subject is enrolled. The coordinator or investigator will then contact the admitting physician to inform them of the subject enrollment and will request that q8 hour serum sodium levels (standard of care) be obtained to monitor for hypernatremia.

4) If the treating physician orders mannitol or additional non-study hypertonic saline infusion (3% saline) for patient care within the first 24 hours, q6 hour serum sodium levels (standard of care for subjects receiving mannitol or 3% saline) will be drawn to monitor for hypernatremia.

4) Any subject requiring hypertonic saline infusion or mannitol boluses beyond 24 hours will have q6 hour sodium monitoring with the last sodium level 6 hours after discontinuation of therapy and/or up to 5 days after injury.

5) A study coordinator and/or investigator will be on call 24 hours a day, 7 days a week to implement the sodium monitoring plan and address any concerns from care providers. The coordinator will also have a 24 hour/7 day a week backup by a ROC investigator physician.

6) Each hospital accepting patients enrolled in the study will have a named physician co-investigator on the medical staff who will be responsible for facilitating communication with study personnel and addressing any concerns regarding patient management.

Parkland Health and Hospital System:	Principle Investigator Trauma Co-Investigator	Ahamed H. Idris, MD Joseph Minel, MD
Baylor University Medical Center:	Co-Investigator Trauma Co-Investigator	Michael Ramsay, MD Michael Foreman, MD
Methodist Medical Center:	Co-Investigator Trauma Co-Investigator	Robert Simonson, DO Alicia Mangram, MD

7) After admission to ICU, the patient's clinical status will be monitored daily by study personnel for the first 5 days after injury and then every other day thereafter. This will include monitoring of sodium levels, screening for potential SAE's and completing data collection forms with respect to the patient's clinical status.

8) All three trauma centers, Parkland, Baylor and Methodist have agreed to follow the GLUE grant or similar clinical care guidelines for managing severely injured patients. Should the study coordinator identify any concerns related to the patient's condition or management, the local investigator or PI will be notified.

9) The ICU medical staff at all three trauma centers will be in serviced regarding the above protocol changes.

B) Risk Analysis Update:

If the overall risk(s) associated with the research as originally stated in the IRB approved application are either increased or decreased, an updated assessment of the risk(s) must be provided. **If the risk profile of the research is unchanged, this should be stated.**

The risk profile is improved. The amendment includes increased monitoring of patient condition and laboratory values.

My signature certifies that I assure compliance with the ethical principles and institutional policies regarding the protection of human subjects in research as stated in Title 45 Code of Federal Regulations Part 46 (revised June 1991; reprinted April 2, 1996) and the Multiple Project Assurance, and that I have reviewed this report for accuracy. In addition, my signature certifies that the proposed changes are necessary for scientific, medical, administrative or disclosure reasons in order to continue the research project as originally described in the IRB application.

Alexander H. [Signature]
Principal Investigator's Signature

11/17/06
Date

Nicole L. Clemis RN
Research Coordinator's Signature

11/17/06
Date

For IRB office use only:

Approved Expedited Review

Reviewer: [Signature]
IRB Chair or Designee

Date: 11/22/06

or for Full Board review

Reviewer: _____
IRB Chair or Designee

Date: _____

Periodic Review Approval

Reviewer: _____

Date: _____

**UT SOUTHWESTERN
MEDICAL CENTER****Institutional Review Board**

TO: Ahamed H. Idris, MD
c/o Dixie Climer
Surgery -- MC # 8579

FROM:  David R. Karp, MD, PhD
Institutional Review Board 1 Chairperson
IRB - 8843

DATE: May 10, 2006

RE: **Final Approval of Protocol, NR1 Form, Project Summary, Consent Form(s), HIPAA Waiver and Acknowledgment of HIPAA Authorization**
IRB Number: 032006-028
Title: Hypertonic Resuscitation Following Traumatic Injury

Thank you for responding to the stipulations as requested by the Institutional Review Board in the memo dated March 27, 2006. This letter is a notification of final approval of the protocol, HIPAA waiver and attached Informed consent document(s) dated May 10, 2006. IRB approval of this research lasts until March 19, 2007. If the research continues beyond twelve months, you must apply for updated approval of the protocol and informed consent document(s) one month before the date of expiration noted above.

Please Carefully Read Important Compliance Information Below:

Your approved number of evaluable subjects is 700. If during the course of your study you feel that you have need to change this number, you must submit a completed MOD Form applying for prospective approval to do so.

All subjects must sign a copy of the attached IRB-approved and stamped consent form(s) and HIPAA Authorization, if applicable, before undergoing any study procedures, including screening procedures that would not otherwise be performed for a patient/subject's medical condition in a non-research context.

The above referenced study is approved to enroll Spanish-speaking subjects. DHHS regulations permit oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally. A witness to the oral presentation is required, and the subject must be given copies of the short form document and the summary.

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Page 2 of 3

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Approval by the appropriate authority at a collaborating facility is required before subjects may be enrolled on this study.