ROC Site Status & Enrollment as of 4/30/2007

San Diego	IRB	Initial IRB Approval	FDA Amendment Approval	IRB Approval to Start	Shock Cohort Enrolled	TBI Cohort Enrolled	Community Consultation Completed
Overarching IRB-UC-San Diego							
Hospitals					14	9	Sep-06
UCSD Medical Center, Hillcrest	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Palomar Hospital Medical Center	Palomar	4/14/2006	2/8/2007	2/8/2007			
Scripps Mercy Hospital	Scripps Mercy	9/26/2006	1/8/2007	1/8/2007			
Scripps Memorial Hospital-La Jolla	Scripps	10/11/2006	12/7/2006	12/7/2006			
Sharp Memorial Hospital	Sharp	9/20/2006	1/17/2007	1/17/2007			
EMS Agencies							
Alpine Fire Protection District	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
American Medical Response	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Barona Fire Department	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Bonita/Sunnyside Fire Protection	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Borrego Springs Fire Protection District	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Carlsbad Fire Department	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Coronado Fire Department	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
CSA-17 ALS Transporting Agency	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Deer Springs	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Del Mar Fire Department	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
East County Fire Protection District	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
El Cajon Fire Department - ALS	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Encinitas Fire Protection District	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Escondido Fire Department - ALS	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Federal Fire Department San Diego	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Imperial Beach Fire Department	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Julian-Cuyamaca Fire Dept. - ALS	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
La Mesa Fire Department	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Lakeside Fire Protection District	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Lemon Grove Fire Dept.	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Mercy Air	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Miramar Fire Department	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
National City Fire Department	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
North County Fire - ALS	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Oceanside Fire Dept. - ALS	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Pala Fire Department	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Poway Fire Dept. - ALS	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Ramona Fire Dept. - ALS	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Rancho Santa Fe Fire Protection District	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
San Marcos Fire Dept. ALS	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
San Miguel Fire Protection District	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			

Santee Fire Dept. - ALS	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Solana Beach Fire Department	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Sycuan Fire Dept. - ALS	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Valley Center/Mercy Ambulance	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Viejas Fire Department	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
Vista Fire Dept. - ALS	UC-San Diego	2/16/2006	11/27/2006	2/1/2007			
All agencies are enrolling							

Shock Enrollment Breakdown as of 4/30/2007	UCSD Medical Center, Hillcrest	Palomar Hospital Med Ctr	Scripps Mercy Hospital	Scripps Memorial Hospital-La Jolla	Sharp Memorial Hospital	Pre-hosp disposition unknown	Total
EMS Agencies/Hospitals							
Alpine Fire Protection District	0	0	0	0	0	0	0
American Medical Response	1	0	0	1	4	0	6
Barona Fire Department	0	0	0	0	0	0	0
Bonita/Sunnyside Fire Protection	0	0	0	0	0	0	0
Borrego Springs Fire Protection District	0	0	0	0	0	0	0
Carlsbad Fire Department	0	0	0	0	0	0	0
Coronado Fire Department	0	0	0	0	0	0	0
CSA-17 ALS Transporting Agency	0	0	1	0	0	0	1
Deer Springs	0	0		0	0	0	0
Del Mar Fire Department	0	0	0	0	0	0	0
East County Fire Protection District	0	0	0	0	0	0	0
El Cajon Fire Department - ALS	0	0	0	0	2	0	2
Encinitas Fire Protection District	0	0	0	0	0	0	0
Escondido Fire Department - ALS	0	0	0	0	0	0	0
Federal Fire Department San Diego	0	0	0	0	0	0	0
Imperial Beach Fire Department	0	0	0	0	0	0	0
Julian-Cuyamaca Fire Dept. - ALS	0	0	0	0	0	0	0
La Mesa Fire Department	0	0	0	0	0	0	0
Lakeside Fire Protection District	0	0	0	0	2	0	2
Lemon Grove Fire Dept.	0	0	0	0	0	0	0
Mercy Air	0	0	1	0	0	0	1
Miramar Fire Department	0	0	0	0	0	0	0
National City Fire Department	0	0	0	0	0	0	0
North County Fire - ALS	0	0	0	0	0	0	0
Oceanside Fire Dept. - ALS	0	0	0	0	0	0	0
Pala Fire Department	0	0	0	0	0	0	0
Poway Fire Dept. - ALS	0	0	0	0	0	0	0
Ramona Fire Dept. - ALS	0	0	0	0	0	0	0
Rancho Santa Fe Fire Protection District	0	0	0	0	0	0	0
San Marcos Fire Dept. ALS	0	0	0	0	0	0	0
San Miguel Fire Protection District	0	0	0	0	0	0	0
Santee Fire Dept. - ALS	0	0	0	0	2	0	2
Solana Beach Fire Department	0	0	0	0	0	0	0
Sycuan Fire Dept. - ALS	0	0	0	0	0	0	0
Valley Center/Mercy Ambulance	0	0	0	0	0	0	0
Viejas Fire Department	0	0	0	0	0	0	0
Vista Fire Dept. - ALS	0	0	0	0	0	0	0
Total for Hospital	1	0	2	1	10	0	14

TBI Enrollment Breakdown as of 4/30/2007	UCSD Medical Center, Hillcrest	Palomar Hospital Med Ctr	Scripps Mercy Hospital	Scripps Memorial Hospital	Sharp Memorial Hospital	Pre-hosp disposition unknown	Total
EMS Agencies/Hospitals							
Alpine Fire Protection District	0	0	0	0	0	0	0
American Medical Response	2	0	1	0	1	0	4
Barona Fire Department	0	0	0	0	0	0	0
Bonita/Sunnyside Fire Protection	0	0	0	0	0	0	0
Borrego Springs Fire Protection District	0	0	0	0	0	0	0
Carlsbad Fire Department	0	0	0	0	0	0	0
Coronado Fire Department	0	0	0	0	0	0	0
CSA-17 ALS Transporting Agency	0	0	0	0	0	0	0
Deer Springs	0	0	0	0	0	0	0
Del Mar Fire Department	0	0	0	0	0	0	0
East County Fire Protection District	0	0	0	0	0	0	0
El Cajon Fire Department - ALS	0	0	0	0	0	0	0
Encinitas Fire Protection District	0	0	0	0	0	0	0
Escondido Fire Department - ALS	0	0	0	0	0	0	0
Federal Fire Department San Diego	0	0	0	0	0	0	0
Imperial Beach Fire Department	0	0	0	0	0	0	0
Julian-Cuyamaca Fire Dept. - ALS	0	0	0	0	0	0	0
La Mesa Fire Department	0	0	0	0	0	0	0
Lakeside Fire Protection District	0	0	0	0	0	0	0
Lemon Grove Fire Dept.	0	0	0	0	0	0	0
Mercy Air	0	0	0	0	0	0	0
Miramar Fire Department	0	0	0	0	0	0	0
National City Fire Department	0	0	0	0	0	0	0
North County Fire - ALS	0	0	0	0	0	0	0
Oceanside Fire Dept. - ALS	0	0	0	0	0	0	0
Pala Fire Department	0	0	0	0	0	0	0
Poway Fire Dept. - ALS	0	0	0	0	0	0	0
Ramona Fire Dept. - ALS	0	1	0	0	0	0	1
Rancho Santa Fe Fire Protection District	0	0	0	0	0	0	0
San Marcos Fire Dept. ALS	0	0	0	0	0	0	0
San Miguel Fire Protection District	0	0	0	0	0	0	0
Santee Fire Dept. - ALS	0	0	0	0	0	0	0
Solana Beach Fire Department	0	0	0	0	0	0	0
Sycuan Fire Dept. - ALS	0	0	0	0	0	0	0
Valley Center/Mercy Ambulance	0	0	0	0	0	0	0
Viejas Fire Department	0	0	0	0	0	0	0
Vista Fire Dept. - ALS	0	2	0	0	0	2	4
Total for Hospital	2	3	1	0	1	2	9

060184

UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

TO: Daniel Davis Mailcode: 8676

RE: Project #060184
Hyperntonic Resuscitation Following Traumatic Injury

Dear Dr. Davis:

The above-referenced project was reviewed and approved by one of this institution's Institutional Review Boards in accordance with the requirements of the Code of Federal Regulations on the Protection of Human Subjects (45 CFR 46 and 21 CFR 50 and 56), including its relevant Subparts. This approval, based on the degree of risk, is for 365 days from the date of **IRB review and approval** unless otherwise stated in this letter. The regulations require that continuing review be conducted on or before the 1-year anniversary date of the IRB approval, even though the research activity may not begin until some time after the IRB has given approval

The IRB reviewed this study ensuring that **all of 21 CFR Part 50.24** Exception from Informed Consent Requirements for Emergency Research were adhered to, including consultation with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn, etc.

This study was reviewed for approval under **45 CFR 46.406** which includes that the research poses greater than minimal risk with no prospect of direct benefit to the child, but is likely to yield generalizable knowledge about the child disorder or condition, the risk represents a minor increase over minimal risk, the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations, and the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition. Per federal guidelines, permission must be obtained from both parents on this study unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

This study was reviewed by the IRB under **46.409**. One individual [the Prisoner's Advocate on the IRB] who has the background and experience to act in, and agrees to act in, the best interests of the prisoner for the duration of the prisoner's participation in the research and who is not associated in any way (except in role of as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

Date of IRB review and approval: 2/1/2007

On behalf of the Institutional Review Board,

/ba

Michael Caligiuri, Ph.D.
Director, Clinical Research Protections Program (CRESP)
(858) 455-5050

Note: All Human Subject research conducted at the VA facility and/or utilizing VA/VMRF funds MUST BE APPROVED by the VA Research and Development Committee prior to commencing any research. In addition, please ensure that the clinical trial agreement or other funding is appropriately in place prior to conducting any research activities. IRB approval does not constitute funding approval.

Approval release date: 2/5/2007

060184

UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

Date: November 27, 2006

To: Daniel Davis Mailcode: 8676

Re: Project #060184
Hyperntonic Resuscitation Following Traumatic Injury

Dear Dr. Davis:

Your request to amend the above study received November 20, 2006, dated November 16, 2006, has been reviewed and approved. This amendment involves revisions in the monitoring principles proposed in consideration of FDA recommendations for additional oversight on inpatient study monitoring. As presented, it is expected that the modifications "will lead to a decrease in patient risk, as adverse events will be captured in an expedited fashion." Your comment that there are no in-hospital interventions involved in this trial was noted.

A copy of the protocol amendment and background correspondence was received, as well as your cover letter outlining this request. This information is now part of the IRB study file.

While the amendment was approved, please revise the local research plan and forward one copy highlighting (bolded) changes, as well as a clean copy as required for all amendment submissions. Please address to HRPP at mail code 0052 or upload to the existing study number utilizing e-irb services at http://irb.ucsd.edu .

On behalf of the UCSD Institutional Review Board,

/mg

Michael Caligiuri, Ph.D.
Director, Clinical Research Protections Program
Mailcode: 0052 Phone: 858-455-5050

060184

UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

TO: Daniel Davis Mailcode: 8642

RE: Project #060184
Hyperntonic Resuscitation Following Traumatic Injury

Dear Dr. Davis:

The above-referenced project was reviewed and approved by one of this institution's Institutional Review Boards in accordance with the requirements of the Code of Federal Regulations on the Protection of Human Subjects (45 CFR 46 and 21 CFR 50 and 56), including its relevant Subparts. This approval, based on the degree of risk, is for 365 days from the date of **IRB review and approval** unless otherwise stated in this letter. The regulations require that continuing review be conducted on or before the 1-year anniversary date of the IRB approval, even though the research activity may not begin until some time after the IRB has given approval.

The IRB reviewed this study ensuring that **all** of 21 CFR Part 50.24 Exception from Informed Consent Requirements for Emergency Research were adhered to, including consultation with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn, etc.

This study was reviewed for approval under 45 CFR 46.406 which includes that the research poses greater than minimal risk with no prospect of direct benefit to the child, but is likely to yield generalizable knowledge about the child disorder or condition, the risk represents a minor increase over minimal risk, the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations, and the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition. Per federal guidelines, permission must be obtained from both parents on this study unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

This study was reviewed by the IRB under 46.409. One individual [the Prisoner's Advocate on the IRB] who has the background and experience to act in, and agrees to act in, the best interests of the prisoner for the duration of the prisoner's participation in the research and who is not associated in any way (except in role of as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

Date of IRB review and approval: 2/16/2006

On behalf of the Institutional Review Board,

/nm

Michael Caligiuri, Ph.D.
Director, Clinical Research Protections Program
(858) 455-5050

Note: All Human Subject research conducted at the VA facility and/or utilizing VA/VMRF funds MUST BE APPROVED by the VA Research and Development Committee prior to commencing any research. In addition, please ensure that the clinical trial agreement or other funding is appropriately in place prior to conducting any research activities. IRB approval does not constitute funding approval.

Approval release date: 9/25/2006

THOMAS S. VELKY, JR, M.D.
GENERAL & VASCULAR SURGERY
DIPLOMATE, AMERICAN BOARD OF SURGERY

215 SOUTH HICKORY STREET, STE 112
ESCONDIDO, CA 92025

TELEPHONE (760) 489-9242
FAX (760) 489-7150

11/20/2006

Title : Hypertonic Resuscitation following Traumatic Injury

To: Dr. Richard Just
Chair, Institutional Review Board
Palomar Pomerado Health

Dear Dr. Just,

The Resuscitation Outcomes Consortium (ROC) Hypertonic Salinei Dextran (HSD) trial was recently approved by your institutional review board. We have not yet begun enrolling patients locally, but other ROC sites initiated the study earlier this year. We recently became aware of concerns from the FDA regarding the level of monitoring within these sites for patients following admission, specifically with regard to the serum sodium values over the first several days of admission. The FDA wants to assure that episodes of hypernatremia, which appear to be a result of diabetes insipidus, are not related to the study fluid. As a result of these concerns, the ROC investigators have reviewed the available literature, which confirms our original contention that the volume of hypertonic fluid being administered as part of this study is not enough to significantly raise serum sodium to concerning levels. In addition, standard operating procedures and guidelines for in-hospital monitoring were created. While these negotiations were conducted, the sites that had initiated the ROC HSD trial voluntarily suspended enrollment.

Included with this letter are the revisions to the protocol as well as the FDA letter accepting this revision. We are hopeful that this can undergo expedited review for several reasons. First, the trauma system in San Diego has already endorsed the monitoring principles proponed in the revised document. In addition, representatives in each trauma center have been identified to oversee inpatient study monitoring. It is worth noting that there are no in-hospital interventions involved in this trial, with the inpatient component involving monitoring and outcomes data collection. Perhaps most importantly, the increased surveillance that will be required as part of the revisions will lead to a decrease in patient risk, as adverse events will be captured in an expedited fashion. We will need a letter from your institutional review board approving these revisions before we can proceed with the trial.

These modifications have been discussed with Dr. Michael Caligiuri, Director of the UCSD Investigational Review Board, who feels that expedited review is appropriate. Please do not hesitate to contact myself or the ROC Coordinator, Donna Kelly at 619-471-0616 with additional questions or comments.

Thank you very much.

Thomas Velky MD
Principal Investigator
Palomar Trauma Director
760/489-9242

Reviewed and approved by the Palomar Pomerado Investigational Review Committee.

Richard G. Just, 2-8-07

Richard G. Just, M.D., Date
Chairman

DEC 1 5 2006

MEDICAL STAFF SERVICES

April 14, 2006

Thomas S. Velky, M.D.
215 S. Hickory Street, Suite 112
Escondido, CA 92025

RE: **Hypertonic Resuscitation Following Traumatic Injury**

Dear Doctor Velky:

The Palomar Pomerado Investigational Review Committee (PPH IRC), in its meeting of February 9, 2006, reviewed and granted conditional approval for the protocol and informed consent for the above-mentioned study pending resolution an issue with the informed consent (see our letter of February 10, 2006). The Committee reviewed your response at the last meeting and is satisfied that the revised informed consent fulfills the recommendations of the Committee. As such, the PPH IRC, in its meeting of April 13, 2006 approved the protocol and informed consent for the above-mentioned study. The study was approved to be conducted at Palomar Medical Center.

Prior to initiation of the study, approval must also be obtained from the Executive Committee and Administration of the Hospital(s) involved. Studies approved by the Investigational Review Committee may not proceed until after Executive Committee and administrative approval is obtained. Please contact Linda Urden, R.N. at (858) 613-4072 for information on the administrative review process. Study specific laboratory and imaging studies that will be performed as part of the study are required to be ordered on the appropriate form.

The Palomar Pomerado Investigational Review Committee is in compliance with Federal Rules and Regulations and operates in accordance with Good Clinical Practices. Approval of this protocol and informed consent is effective for one (1) year from the initial approval and may not proceed past April 13, 2007 without reapproval by the Investigational Review Committee.

Sincerely,

Richard G. Just, M.D.
Chairman, Investigational Review Committee

☑ PALOMAR MEDICAL CENTER
555 East Valley Parkway
Escondido, CA 92025
Tel 760.739.3140
Fax 760.739.2026

☐ POMERADO HOSPITAL
15615 Pomerado Road
Poway, CA 92064
Tel 858.613.4664
Fax 858.613.4217

☐ ESCONDIDO SURGERY CENTER
343 East Second Avenue
Escondido, CA 92025
Tel 760.480.6606
Fax 760.480.1288

Scripps

Office for the Protection of Research Subjects

Scripps Mercy IRB
10150 Sorrento Valley Rd, Suite 330
San Diego, CA 92121

Approval Notice (Modification)

Investigator:	Michael Sise, M.D.
Department:	Trauma Service Mercy
Project Title:	Resuscitation Outcomes Consortium (ROC): Hypertonic Resuscitation Following Traumatic Injury Trial
Protocol No:	M0-6-005
Risk Category:	II Full Board Review - Greater than Minimal Risk
Date of Review:	1/8/2007
Type of Review:	Modification

The modification to the protocol above was reviewed and approved by the Committee or one of its officers. This modification does not extend the expiration date of the protocol, which is the date of original review.

(Amendment dated 12-15-06 increases the level of monitoring of subject's blood sodium levels, in response to FDA concerns)

Barbara J. Bishop
IRB Officer

The Scripps Mercy IRB is registered with OHRP as Scripps Health Mercy IRB# 4 (IRB00004337).
Scripps holds FWA # FWA00007338.

Scripps

Office for the Protection of Research Subjects

Scripps Mercy IRB
10150 Sorrento Valley Rd, Suite 330
San Diego, CA 92121

Approval Notice

Investigator:	Michael Sise, M.D.
Department:	Trauma Service Mercy
Project Title:	Resuscitation Outcomes Consortium (ROC): Hypertonic Resuscitation Following Traumatic Injury Trial
Protocol No:	**M06-005** 2006 - MER
Risk Category:	II Full Board Review - Greater than Minimal Risk
Date of Review:	9/26/2006
Type of Review:	Full Board Review NEW

Your research project indicated above was reviewed and approved by the IRB or one of its officers on the review date above. Approval expires one year from this date.

Approval carries with it the understanding that you will inform the Committee promptly should a serious adverse reaction occur, and that you will make no modification to the protocol or consent form without prior approval of the Committee.

The IRB may suspend or terminate the approval of research that is not being conducted in accordance with the requirements set forth by the committee or that has been associated with unexpected serious harm to subjects.

(Protocol dated 11/08/05; Investigator's Brochure, Edition 02, Release Date June 30, 2004; case report forms dated 6/26/06; 6 consent forms, all with a version date of 8/30/06, including: Subject, Parental and Assent forms for hypovolemic injury; Subject, Parental and Assent for severe traumatic brain injury; Scripps HIPAA Authorization.)

Thank you for your cooperation.

IRB Officer

The Scripps Mercy IRB is registered with OHRP as Scripps Health Mercy IRB# 4 (IRB00004337).
Scripps holds FWA # FWA00007338.

Office for the Protection of Research Subjects

Scripps Memorial La Jolla IRB
10150 Sorrento Valley Rd, Suite 330
San Diego, CA 92121

Approval Notice (Modification)

Investigator:	Gail T Tominaga, M.D.
Department:	
Project Title:	(ROC) Resuscitation Outcomes Consortium: Hypertonic Resuscitation Following Traumatic Injury Trial
Protocol No:	L0-6-003
Risk Category:	II Full Board Review - Greater than Minimal Risk
Date of Review:	12/7/2006
Type of Review:	Modification

The modification to the protocol above was reviewed and approved by the Committee or one of its officers. This modification does not extend the expiration date of the protocol, which is the date of original review.

(Amendment dated 11-27-06 increases the level of monitoring of subject's blood sodium levels, in response to FDA concerns)

IRB Officer

The Scripps Memorial La Jolla IRB is registered with OHRP as Scripps Health La Jolla IRB#3 (IRB00004326).
Scripps holds FWA # FWA00007326.

Scripps

Office for the Protection of Research Subjects

Scripps Memorial La Jolla IRB
10150 Sorrento Valley Rd, Suite 330
San Diego, CA 92121

Approval Notice

Investigator:	Gail T Tominaga, M.D.
Department:	Trauma Service La Jolla
Project Title:	(ROC) Resuscitation Outcomes Consortium: Hypertonic Resuscitation Following Traumatic Injury Trial
Protocol No:	004299 L0-6-003 2006 - LAJ
Risk Category:	II Full Board Review - Greater than Minimal Risk
Date of Review:	10/11/2006
Type of Review:	Full Board Review NEW

Your research project indicated above was reviewed and approved by the IRB or one of its officers on the review date above. Approval expires one year from this date.

Approval carries with it the understanding that you will inform the Committee promptly should a serious adverse reaction occur, and that you will make no modification to the protocol or consent form without prior approval of the Committee.

The IRB may suspend or terminate the approval of research that is not being conducted in accordance with the requirements set forth by the committee or that has been associated with unexpected serious harm to subjects.

(Protocol dated 11/08/05; Investigator's Brochure, Edition 02, Release Date June 30, 2004; case report forms dated 6/26/06; 6 consent forms, all with a version date of 8/30/06, including: Subject, Parental and Assent forms for hypovolemic injury; Subject, Parental and Assent for severe traumatic brain injury; Scripps HIPAA Authorization.)

Thank you for your cooperation.

IRB Officer

The Scripps Memorial La Jolla IRB is registered with OHRP as Scripps Health La Jolla IRB#3 (IRB00004336).
Scripps holds FWA # FWA00007338.

SHARP
HEALTH CARE

January 17, 2007

Frank Kennedy, MD
7901 Frost Street
San Diego, CA 92123

RE: **Hypertonic Resuscitation Following Traumatic Injury**
IRB# 060394

Dear Doctor Kennedy:

This letter is notification that the Sharp HealthCare Institutional Review Board (IRB) approved the following item for the above-referenced research study at the January 17, 2007 meeting:

- Protocol Revision 11/22/2006

If you have any other changes or amendments, please submit them to the Board for review in order to ensure the continuation of your research project. Please contact the IRB Office at (858) 499-4836 if you have any questions. Thank you.

Sincerely,

David Bodkin, M.D.
Chair, IRB
Sharp HealthCare

David Willms, M.D.
Vice-Chair, IRB
Sharp HealthCare

Caryn Burgess
IRB Manager
Sharp HealthCare

SHARP ORGANIZATIONS
San Diego Hospital Association Sharp Memorial Hospital Grossmont Hospital Corporation Sharp Chula Vista Medical Center
Sharp Coronado Hospital and HealthCare Center Sharp Mesa Vista Hospital Sharp Mary Birch Hospital For Women
Sharp Vista Pacifica Sharp Mission Park Medical Centers Sharp Rees-Stealy Medical Centers Sharp Health Plan
SCMG Corporation Sharp HealthCare Foundation Grossmont Hospital Foundation Coronado Hospital Foundation
8695 Spectrum Center Court San Diego, California 92123-1489

SHARP

October 02, 2006

Frank Kennedy, MD
7901 Frost Street
San Diego, CA 92123

RE: **Hypertonic Resucitation Following Traumatic Injury**
IRB# 060394

Dear Doctor Kennedy:

This is notification that the Sharp HealthCare Institutional Review Board (IRB) has approved your application, dated 11/8/2005 (4) Consent Documents: Priamry, Parental, and Assent, and informed consent document, and PHI authorization dated 8/30/2006 for the above-referenced research study at the September 20, 2006 meeting.

The following site and investigators are approved:

Site:
Memorial

Principal Investigator:
Frank Kennedy, MD

Study Coordinator:
Donna Kelly

Sub-investigator:
Hoyt, David B MD
Daniel Davic, MD

Your IRB approval reference number is 060394. Please include this reference number in all of your future correspondence and reporting to the IRB Office. As a reminder, it is the responsibility of the principal investigator to submit status reports to the Institutional Review Board. Your IRB approval expires February 16, 2007. You must submit a status report by Friday, January 5, 2007 in order to ensure the continuation of your study. If you have any amendments, revisions, or changes to the protocol or informed consent, please submit them to the Institutional Review Board for approval. In addition, all patient recruitment materials must be submitted to the Board for approval prior to their use.

It is the policy of Sharp HealthCare Institutional Review Board that the Principal Investigator(s) submit a copy of their reports, findings, or manuscripts to the Board prior to publication. Sharp HealthCare would expect that if the results of the research project came to publication, their role would be properly recognized in the research.

Please contact the IRB Office if you have any questions at (858) 499-4836.

Sincerely,

David Bodkin, M.D.
Chair, Institutional Review Board
Sharp HealthCare

SHARP ORGANIZATIONS
San Diego Hospital Association ▪ Sharp Memorial Hospital ▪ Grossmont Hospital Corporation ▪ Sharp Chula Vista Medical Center
Sharp Coronado Hospital and HealthCare Center ▪ Sharp Mesa Vista Hospital ▪ Sharp Mary Birch Hospital For Women
Sharp Vista Pacifica ▪ Sharp Mission Park Medical Centers ▪ Sharp Rees-Stealy Medical Centers ▪ Sharp Health Plan
SCMG Corporation ▪ Sharp HealthCar Foundation ▪ Grossmont Hospital Foundation ▪ Coronado Hospital Foundation

San Diego County Community Consultation and Public Notification
ROC Hypertonic Saline Resuscitation following Traumatic Injury Table Report

ROC Participant	Type of Event	Event Date	Response and Comment
General Public Notification			
Hebert Research Inc.	Telephone survey	Week of June 6th to 14th 2006	A telephone survey was done by the Hebert Research from Belleview, Washington to assess what San Diegans felt about this type of research being done in their community. The company surveyed 502 persons in English and Spanish through out the county. This company is familiar with ROC and have done similar surveys for the Seattle ROC site, the Portland ROC site, Milwaukee ROC site and the Dallas ROC site. Survey results for San Diego were that the overall response to doing this type of research is well accepted with 80% respondents would not object to being included in this HSD trial. There were no trends in potential issues raised by the public. Full report enclosed.
UCSD Public Relations	UCSD Press Release	July 27th 2006	Press release from UCSD with general information on ROC and the research intended. This was distributed to local newspaper reporters. As a result the North County Times Newspaper interviewed Dr. Daniel Davis and printed a story about UCSD's participation in ROC on August 13th 2006. The article was favorable and explained how the county will work together in this venture with UCSD leading the program. Copy enclosed. The press release was also posted to the public UCSD website and highlighted on the main web page as well as being posted to the UCSD Healthcare webpage. Copies of both enclosed.
Dr. Daniel Davis /UCSD Public Relations	Interview with Carol LeBeau Channel 10 local news coverage	July 28th 2006	Aired on "Staying Healthy" Saturday July 28th 2006 at 5:00 pm on evening news program and posted to their web site.
UCSD ROC Staff	Newspaper advertisement	Union Tribune, North County Times, La Prensa, Voice	Advertisements were taken out in five different local newspapers including two with a Hispanic circulation, one with a Filipino circulation, two with general county wide circulation. Stated what ROC

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ROC Hypertonic Saline Resuscitation following Traumatic Injury Table Report

ROC Participant	Type of Event	Event Date	Response and Comment
		and Viewpoint, El Latino, Filipino Press July 30th to August 5th 2006 (See attached Grid)	is and what types of clinical trials would be conducted. Invitation to community meetings with dates times and addresses included. Union Tribune also placed the advertisement on their website "SignOnSanDiego.com " for one week. Copy of newspapers and print dates enclosed.
Dr. Daniel Davis	Chula Vista Library Community Meeting	August 16th 2006 6:30 pm to 7:30 pm	Attended by ROC staff of Dr. Davis, Dr. Dunford, Lana McCallum Brown and Donna Kelly. Single participant attended and the program was discussed with him. Reviewed hand out and he completed the questionnaire with being in favor of doing this type of research in San Diego. Since the presentation was informal questions related to trials were answered as they came up. Handouts and brochures available for any participant at the door. Copies enclosed.
Dr. Daniel Davis	Carlsbad Library Community Meeting	August 17th 2006 10:30 am to 11:30 am	Attended by ROC staff of Dr. Davis, Lana McCallum Brown and Donna Kelly. Two participants attended and formal presentation presented by Dr. Davis. Open questions related to trials answered through out presentation and surveys from both participants were obtained, both in favor of doing this type of research in San Diego. Handouts and brochures available for any participant at the door.
Dr. Daniel Davis	Poway Library Community Meeting	August 17th 2006 2:30 pm to 3:30 pm	Attended by ROC staff of Dr. Davis, Dr. Raul Coimbra, Lana McCallum Brown and Donna Kelly. Participation was limited to two persons. One from the San Diego County EMS office and one from California Assemblywoman Lori Saldana's office. Both these individuals were already very familiar with ROC and the upcoming trials so the discussion was left informal and general questions about this type of research were discussed. There were no surveys completed. Handouts and brochures available for any participant at the door.
Dr. Daniel Davis	El Cajon Library Community Meeting	August 18th 2006 2:30 pm to 3:30	Attended by ROC staff of Dr. Davis, Lana McCallum Brown and Donna Kelly. There were three

San Diego County Community Consultation and Public Notification
ROC Hypertonic Saline Resuscitation following Traumatic Injury Table Report

ROC Participant	Type of Event	Event Date	Response and Comment
		pm	participants attending. Formal presentation given and questions during and after answered. All 3 participants completed surveys and there were no objections to doing this type of research in San Diego. Handouts and brochures available for any participant at the door.
Dr. Daniel Davis	Interview with Union Tribune Reporter Cheryl Clarke	August 30th 2006	Article to be printed in the Union Tribune on what ROC is and how it will help the future of Trauma and Cardiac Arrest survival. To go to print in September.
Medical Community			
Dr. David Hoyt and Dr Raul Coimbra, both ROC Co investigators	Medical Advisory Committee (MAC)	Monthly updates to the San Diego County trauma directors and County EMS (third Monday of the month)	The group includes the Trauma Directors for all the major trauma centers in the San Diego County area. Dr. Hoyt was the previous P.I to the HSD trail and is now a co investigator since having accepted a position of Chair of Surgery, UC Irvine. Dr. Coimbra is also a co investigator to the HSD trial and now the UCSD Medical Center. Over the past year various discussions occurred at these meetings related to ROC and the feasibility of doing the research and following the care guidelines within the protocol. All Trauma Directors have agreed to participate.

San Diego County Community Consultation and Public Notification
ROC Hypertonic Saline Resuscitation following Traumatic Injury Table Report

ROC Participant	Type of Event	Event Date	Response and Comment
Dr. Daniel Davis	San Diego County Base Hospital Physician Committee (BHPC)	Monthly meetings to advise and set policy for San Diego County Medical Director. (third Tues of the month)	This group includes the base hospital physicians and nurses, county and city EMT educators, and San Diego County EMS office. Over the past year there have been updates to this group By Dr. Davis who is a regular member as he is the Mercy Air Medical Director as well as the P.I. for ROC. Input from this group has help determine the ability of the research to be done across the county. Questions have been answered as they updates have been provided. There have been no major objections from this group to do this research in San Diego County.
Donna Kelly and Lana McCallum Brown, ROC Research Coordinators	Personal contact with each fire department and first responder agency in San Diego County	Ongoing since October 2004	Contacts have been made with all 39 first responding agencies in San Diego County by the ROC coordinators to explain personally what ROC is and how they can participate in the trial. All agencies have provided what ever information was requested of them related to location, personnel, types of responders available at their locations, types of equipment available to them and so on. There have been no objections voiced by any of the agencies and all are anxious to participate in the trial.
Dr. Daniel Davis and Lana Brown, ROC coordinator	Special Meeting to explain ROC to Scripps Mercy physicians and staff	July 5th 2006	Drs. Daniel Davis and Michael Sise met with Cardiology Research Nurse Nancy Grey RN, Chief of Staff for Scripps Mercy Hospital Davis Cracoft Chief of Staff for Scripps Mercy Hospital, Administrative Director Patricia Untied, Emergency Department Nurse Manager Jackie Saucier, Physician Educator Beth Sise and ROC Coordinator Lana Brown.

San Diego County Community Consultation and Public Notification
ROC Hypertonic Saline Resuscitation following Traumatic Injury Table Report

ROC Participant	Type of Event	Event Date	Response and Comment
Dr. Gary Vilke, ROC Co investigator	Scripps Mercy Medical Staff Grand Rounds	July 25th 2006	The trails and ROC were presented at the medical staff grand rounds. There were twenty participants including Trauma physicians and nurses, Orthopedic surgeons, Anesthesiologists, Plastic surgeons and Emergency Medicine physicians who attended. There was strong support voiced from the group.
San Diego ROC Staff	All Trauma Directors and IRB Administrators personal email	July 31st 2006	Email invitations were sent to all the directors of the five trauma facilities and all the IRB Administrative Directors informing them of the schedule of community meetings to take place over the following week. An open invitation was extended to them and anyone they thought might have interest in attending any of the meetings including all the IRB members. There were no participants relating any connection to this group attend any of the community meetings.
Dr. Daniel Davis	Scripps La Jolla Medical Grand Rounds.	August 24th 2006	Scripps La Jolla Medical Grand Rounds featured Dr. Daniel Davis' talk on what ROC is and what the upcoming HSD trial is about. Approximately twenty participants attended including Trauma physicians and nurses, Anesthesiologists and Neurosurgeons. There was 100% approval voiced from the participants to do this type of research and to support the HSD trial.
Dr. Daniel Davis	San Diego County EMT-P and EMT-D contact including EMS agency medical oversight personnel	Summer of 2005 to current	Dr. Davis has been training and conversing with the San Diego County EMT-P (paramedics) and EMT-D in a one on one environment for the past year. The discussions relate to the importance of doing research to improve their patient's outcomes and the science behind why this is beneficial to participate in and perform the trials correctly. The medics have voiced being excited about participating with this protocol and feel that what is being asked of them is not over burdensome.

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ROC Hypertonic Saline Resuscitation following Traumatic Injury Table Report

ROC Participant	Type of Event	Event Date	Response and Comment
Elected Officials			
Dr. James Dunford, ROC Co Investigator and San Diego Fire Department EMS Medical Director, Dr David Hoyt and Dr Daniel Davis	San Diego City Structures meeting	December 12th 2005	Initial meeting set up by Dr. Dunford to introduce the concept of ROC and introduce the ROC staff to some of the city officials that will be involved with ROC. Attending was Joey Sanchez, City Attorney, Donna Goldsmith City ALS/EMS Coordinator, Criss Brainard San Diego Fire Chief, Several of the EMT instructors and the ROC staff. The meeting was well attended with approximately 35 persons attending, mostly from San Diego Fire Department. The concept of research at the field level was discussed and overall agreed that it was something that could be perused.
UCSD Public Relations Sarah Steinhoffer	Council member Donna Frye forward the press release from UCSD	July 27th 2006	No comment returned from this council member.
Dr. James Dunford, ROC Co Investigator and San Diego Fire Department EMS Medical Director		April 2006 to present	Dr Dunford has been meeting with representatives of the Mayor's office updating the office with the progress of what will be required on behalf of the city and the San Diego Fire Department.
Dr. Bruce Haynes, San Diego County Emergency Medical Services (EMS) Medical Director and Carmel Angelo RN, San Diego County EMS Interim Director	Meetings with San Diego County Board of Supervisors and Public Health Officials	Ongoing meetings over past 9 plus months	Dr. Haynes is the San Diego County EMS Medical Director and has been involved with ROC since he took office at the beginning of this year. He has attended multiple meetings with the County Board of Supervisors and between he and Carmel Angelo the information they receive. Dr. Haynes and Ms. Angelo both regularly attend the Medical Advisory Committee (MAC) and the Base Hospital Physician Committee (BHPC) as well as having frequent direct contact with Dr. Daniel Davis, ROC P.I. They have shared the information from these meetings with the board so that the board can remain informed of the trials being presented, the exception to informed consent issues and the potential impact on the community. There have

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ROC Hypertonic Saline Resuscitation following Traumatic Injury Table Report

ROC Participant	Type of Event	Event Date	Response and Comment
			been no reports back that issue exist. Dr Haynes has provided a letter of support for this project to UCSD HRPP.
UCSD Public Relations, Sarah Steinhoffer and Dr. Daniel Davis	Meeting with Lori Saldana, Assemblymember, 76th District	August 11th 2006	Meeting with Assemblymember Saldana was held in her office with herself, Melanie Cohn, her Field Representatives, Dr. Davis, ROC PI., Donna Kelly RN, ROC coordinator, Dr. Michael Caligiuri, UCSD HRPP Director, Leslie Franz, UCSD Public Relations. This was a follow up meeting as there had been a tour of UCSD trauma facility and emergency department the week prior with Drs. Raul Coimbra, James Dunford and Daniel Davis with Assemblymember Saldana. There was no objection to this kind of research on behalf of Ms. Saldana. Issues raised were more related to how do we let the public be aware of this.

San Diego Hebert Survey June 2006

Format – random-digit dialing throughout San Diego County by zip code

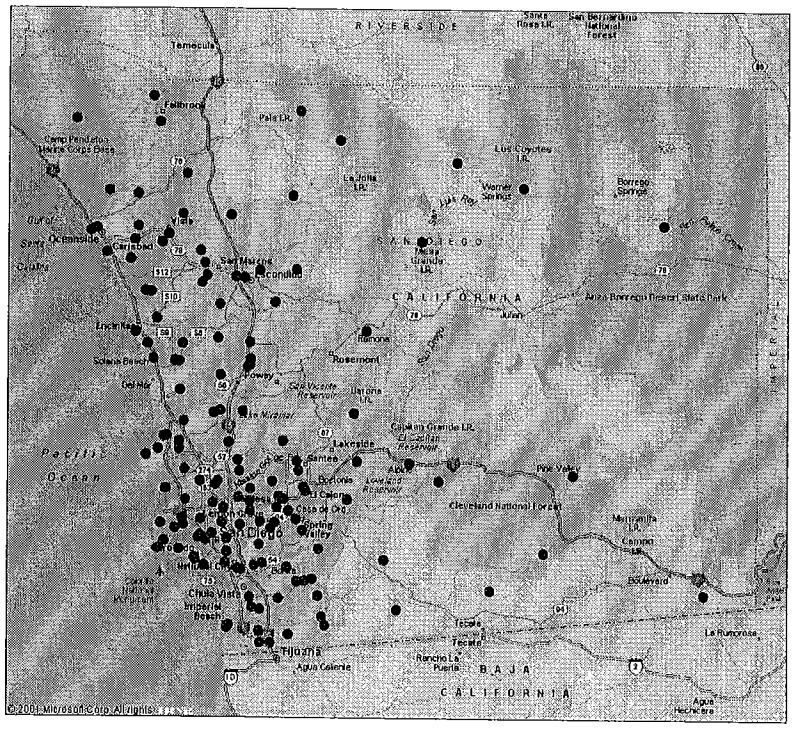
A total of 502 surveys were completed with adults living in the households contacted. Respondents were surveyed proportionate to population by zip code throughout the designated population area for the study (see map). The response rate, which represents the proportion of the population who agreed to participate in the research, was 32.6% percent. The overall incidence rate, which represents the proportion of the population qualified to participate in the full survey, was 100 percent. The maximum margin of error at 502 respondents is +/-4.4 percent.

Of the 502 surveys, approximately 60 surveys (12.0%) were conducted in Spanish. These surveys were conducted in Spanish in the event that a research assistant reached a household that was Spanish-speaking. The assistant then transferred the call to a Spanish-speaking research assistant, who completed the survey with the respondent.

Nearly three-quarters (74.3%) of respondents said they would want the fluid administered to them without providing written consent if they were unconscious, family was not reachable, and they had a one in three chance of dying. Only 19.7% of the respondents said they would *not* want the fluid administered. 6.0% of respondents said they did not know. The community is highly in favor of receiving the experimental fluid in a situation where consent cannot be provided.

Age	Percentage
18 – 24	**11.8%**
25 – 34	**20.3%**
35 – 44	**20.5%**
45 – 54	**18.2%**
55 – 64	**11.5%**
65 and over	**14.5%**
Refused	**3.2%**

Gender	Percentage
Male	**49.1%**
Female	**50.9%**



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UCSD Resuscitation Director
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Date: July 18th, 2006

To: Dr. Michael Caligiuri
Director HRPP

Project: #060184

Name: Hypertonic Resuscitation Following Traumatic Injury

Dr. Caligiuri,

This letter is to report the activities and findings of the community consultation and public notification process for the above mentioned protocol as required for the exception to informed consent.

The process of reaching out to the various communities in San Diego County began with sharing the protocol concepts with the physicians who are the trauma directors for the major trauma hospitals in the county at the Medical Advisory Committee (MAC). This committee includes all the trauma directors, their trauma coordinators and the San Diego County EMS Medical Director and Interim EMS Director. The communication was initiated in the summer of 2004 when San Diego was anticipated to be accepted by the Resuscitation Outcomes Consortium (ROC) Executive Committee as being a site and active contributor to ROC. Once a trauma protocol was selected, it was essential that the trauma directors agree upon its feasibility and express their support. This support was garnered by Dr. David Hoyt, who at the time was the principal investigator for the San Diego ROC grant, a very influential member of ROC, and Co-chair of MAC. He was also Trauma Director and Interim Chair of Surgery for UCSD at that time. Within the past three months, Dr. Hoyt has relocated to Irvine after accepting the position of Chair of Surgery at UC Irvine. He remains active within ROC as a co-investigator at the San Diego ROC site and as ROC Steering Committee Trauma Co-Chair. Dr Hoyt initiated the process of community consultation and public notification while still at UCSD.

As of July 2006 I have accepted the role of PI at the San Diego ROC site and have completed the process initiated by Dr. Hoyt. This transition has been relatively seamless, as I was previously involved in the San Diego ROC site as co-PI, and am well versed in the requirements of

this protocol and the responsibilities as the San Diego ROC site PI. I too am very active within ROC as Chair the EMS Operations Committee and a member of multiple other ROC committees.

One of the first activities related to informing the community about ROC and the potential protocols came from the National Institute of Health (NIH) with their March 24, 2006 press release. The intent of this press release was to let the national public know about ROC, the support from the National Heart Lung and Blood Institute (NHLBI), the participating sites, and how this research is anticipated to help major trauma and cardiac arrest victims. That press release is included in this packet.

The UCSD Public Relations department has become quite familiar with ROC and has been actively involved in the community notification process. They authored the local press release and distributed it to the San Diego news media on July 27th 2006. On August 13, 2006 the North County Times interviewed myself and wrote an article about ROC and how it will integrate with other local hospital initiatives to improve patient care in trauma and cardiac arrest. In addition, Cheryl Clark from the Union Tribune is conducting a series of interviews with myself to run later this month.

The UCSD Public Relations Department also contacted a local television station, which sent a crew to UCSD to film an interview with myself and reporter Carol LeBeau. This was aired on July 28, 2006 at 5:00 p.m. on the Channel 10 news as a "Staying Healthy" feature. Channel 10 also posted the information on their website. A copy of that information is included in this packet.

Community meetings were arranged in various parts of the county including, Chula Vista Library (Wednesday, August 16, 2006), Carlsbad Library (Thursday, August 17, 2006), San Diego Library, Poway Branch (Thursday, August 17, 2006), and El Cajon Library (Friday, August 18, 2006). These meetings varied in time of day and day of week and were located at libraries for easily access and parking. The meeting rooms were arranged so that handouts and sign in sheets were readily available at the door, and a ROC staff member was present to greet each person as they arrived. Space was allotted for large audiences with plenty of seating. The presentation was provided by PowerPoint and the handout matched the presentation. The same survey that was performed by the Hebert Research group for the telephone survey was also given out to all participants at the community meetings. All participants completed the surveys after having seen the presentation.

Newspaper advertisements were purchased to promote ROC and the community meetings two weeks in advance of the meeting dates. The larger newspapers (Union Tribune – July 30th and August 1st and North County Times on August 8th and August 6th) have a combined circulation of approximately 500,000 per day and are read widely across the county. In addition, the advertisement was translated into Spanish and placed in two newspapers (La Prensa – August 4th and El Latino – August 4th) with a combined circulation of 130,000. An advertisement was also placed in a well known Filipino newspaper (The Filipino Press – August 5th) with a circulation of 25,000 per issue, and the Voice and Viewpoint (August 3rd), with a circulation of 25,000 per issue. Despite these efforts, there was a relatively low turn-out to these meetings. Surveys were provided to all participants and collected after the meetings, with none of the participants declining to participate in the trials.

In the interim there were ongoing discussions with various levels of the EMS community. Both the Medical Advisory Committee, involving the trauma directors, and the Base Hospital Physician Committee, involving the San Diego County EMS, base hospital physicians, and EMS nurse coordinators, were updated monthly. Presentations were given at both these meetings so that

everyone involved was kept informed and understood what progress had been made. Special meetings were requested by some of the hospitals so that persons and physicians not routinely attending these meetings were also informed about ROC the pending trials. Additional detail can be found in the enclosed table.

The Emergency Medicine Services (EMS) paramedics and EMT's have been visited by myself throughout 2005 and early 2006. This provided a face-to-face opportunity with the medics and was also used to discuss the idea of research at the EMT level and its importance. The medics have consistently demonstrated strong enthusiasm to participate in the ROC initiatives, which promise to have a substantial impact on patient outcomes. All county EMS agencies have been contacted by ROC staff and have voiced strong enthusiasm for this research, with no agencies declining to participate. This includes the private agency, American Medical Response (AMR), with a letter of support provided by their Medical Director, Dr. Brad Swartz.

The elected officials of San Diego County have also been informed about ROC and the initial trial. Dr. Bruce Haynes, San Diego County EMS Medical Director and Carmel Angelo, San Diego County EMS Interim Director regularly attend the MAC and BHPC meetings and have shared this information with the San Diego County Board of Supervisors and San Diego County Public Health Officials. Dr Haynes has provided a letter of support for ROC on behalf of San Diego County EMS.

UCSD Public Relations Department invited Assemblymember Lori Saldana (District 76) to UCSD for a tour of the trauma and emergency department facilities. This was followed by a meeting at her office on August 11, 2006 to discuss ROC and the trial in more detail. She did not voice major concerns about the trial or how it was conducted but wanted to assure that her constituents were fairly represented and informed about this trial on an ongoing basis. She expressed that this type of research should be encouraged and helped to brainstorm strategies to improve community engagement.

UCSD Public Relations also shared the press release with City Councilmember, Donna Frye, with no specific comments received in response.

Dr. James Dunford, ROC co-investigator and Medical Director for the City of San Diego, has been part of the San Diego ROC site since the beginning. He has kept the San Diego City Council and Mayor's office informed about ROC and how the trial will be conducted in the city. There was an initial meeting on December 12, 2005 to introduce the ROC study group to the City of San Diego attorney, Joey Sanchez, the city ALS/EMS coordinator, Donna Goldsmith, and several of the EMT educators and San Diego Fire Department chiefs. This included a total of approximately 35 participants, with the overall consensus at that time to proceed with plans to include the San Diego City Fire Department in the research plan for the County. Ongoing discussions between ROC and the city council and mayor's office are continuing and should be completed soon.

The trauma hospital administrations were informed through the various individual IRB processes at Scripps Mercy Healthcare, Scripps La Jolla Healthcare, Sharp Health Care, and Palomar Pomerado Health Care. All the above mentioned IRB's have fully reviewed this trial on behalf of each of their facilities, with no major objections put forth and only minor clarifications requested. Each of these IRB approvals are pending full approval from the UCSD IRB. One week prior to the community meetings, emails were sent to all IRB Administrative Directors and their associated Trauma Directors inviting them and anyone they thought might have interest to attend one of the community meetings.