

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

	IRB	IRB Approval to Start	FDA Amendment Approval	Shock Cohort Enrolled	TBI Cohort Enrolled	Community Consultation Completed
Pittsburgh	IRB					
Overarching IRB-University of Pittsburgh						
Hospital				0	0	Jul-06
Allegheny General	Allegheny General	pending				
Mercy Hospital of Pittsburgh	Mercy Hospital of Pittsburgh	pending				
University of Pittsburgh	University of Pittsburgh	7/25/2006	1/16/2007			
EMS Agencies						
City of Pittsburgh EMS	University of Pittsburgh	7/25/2006	1/16/2007			
Mutual Aid Ambulance	Excelsa	pending				
STAT Medivac*	University of Pittsburgh	7/25/2006	1/16/2007			
Washington Ambulance & Chair	Washington Hospital	pending				

*only agency enrolling subjects; only agency able to ascertain that subjects can only go to U of Pittsburgh (only hospital with IRB approval)

Shock Enrollment Breakdown as of 4/30/2007						
				Died in the Field	Total	
EMS Agencies/Hospitals						
City of Pittsburgh EMS	Allegheny	Mercy	U of Pittsburgh	0	0	
Mutual Aid Ambulance	0	0	0	0	0	
STAT Medivac*	0	0	0	0	0	
Washington Ambulance & Chair	0	0	0	0	0	
Total for Hospital	0	0	0	0	0	

TBI Enrollment Breakdown as of 4/30/2007						
				Died in the Field	Total	
EMS Agencies/Hospitals						
City of Pittsburgh EMS	Allegheny	Mercy	U of Pittsburgh	0	0	
Mutual Aid Ambulance	0	0	0	0	0	
STAT Medivac*	0	0	0	0	0	
Washington Ambulance & Chair	0	0	0	0	0	
Total for Hospital	0	0	0	0	0	



**University of Pittsburgh
Institutional Review Board**

3500 Fifth Avenue
Ground Level
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)

MEMORANDUM

TO: Samuel Tisherman, MD
FROM: Margaret Hsieh, MD, Vice Chair *Margaret Hsieh /MH*
DATE: January 22, 2007
SUBJECT: IRB# 0603087: Hypertonic Resuscitation Following Traumatic Injury (ROC)

The Institutional Review Board reviewed the recent modifications to your protocol and consent form(s) at the Full Board Meeting (Committee B) that met on Tuesday, January 16, 2007. These modifications are now approved.

Please include the following information in the upper right-hand corner of all pages of the consent form:

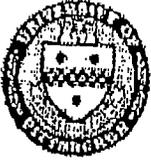
Current Approval Date: July 25, 2006
Modification Approval Date: January 16, 2007
Renewal Date: July 24, 2007
University of Pittsburgh
Institutional Review Board
IRB #0603087

The protocol and consent forms, along with a brief progress report must be resubmitted at least one month prior to the renewal date noted above for annual renewal as required by FWA00006790 (University of Pittsburgh, FWA00006735 (University of Pittsburgh Medical Center), and FWA00000600 (Children's Hospital of Pittsburgh).

If your research proposal involves an investigational drug, please forward a copy of this approval letter along with a copy of the Cover Sheet, protocol, consent form(s) and drug brochure to Investigational Drug Service, PUH Pharmacy.

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

MHdj



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MEMORANDUM

TO: Samuel A. Tisherman, MD
FROM: Richard Guido, MD, Chair *R Guido*
DATE: August 28, 2006
SUBJECT: IRB #0603087: Hypertonic Resuscitation Following Traumatic Injury (ROC)

Thank you for addressing the concerns of the Institutional Review Board regarding the above-referenced proposal. This version of your protocol and consent form(s) has been approved by Committee D.

PLEASE NOTE: The Committee determined that the requirements for exception from informed consent for emergency research detailed in 21 CFR 50.24 have been met. The IRB has approved a waiver (8.3.4) of HIPAA authorization requirement for the sharing of contact information.

Please include the following information in the upper right-hand corner of all pages of the consent form:

Approval Date: July 25, 2006
Renewal Date: July 24, 2007
University of Pittsburgh
Institutional Review Board
IRB #0603087

Please note that it is the investigator's responsibility to report to the IRB any unanticipated problems involving risks to subjects or others [see 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)]. The IRB Reference Manual (Chapter 3, Section 3.3) describes the reporting requirements for unanticipated problems which include, but are not limited to, adverse events. If you have any questions about this process, please contact the Adverse Events Coordinator at 412-383-1504.

The protocol and consent forms, along with a brief progress report must be resubmitted at least one month prior to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006736 (University of Pittsburgh Medical Center), FWA00006600 (Children's Hospital of Pittsburgh), FWA00003667 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

If your research proposal involves an investigational drug, please forward a copy of this approval letter along with a copy of the Cover Sheet, protocol, consent form(s) and drug brochure to Investigational Drug Service, PUH Pharmacy.

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

RG:dj

