



ROCKY
MOUNTAIN
REGIONAL
TRAUMA
CENTER
DENVER HEALTH

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June 30, 2003

Colorado Multiple Institutional Review Board
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Christopher B. Colwell, M.D.
*Medical Director, Paramedic Division &
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RE: COMIRB Protocol Number 03-229

A PHASE III, RANDOMIZED, CONTROLLED, OPEN-LABEL, MULTI-CENTER, PARALLEL GROUP STUDY USING PROVISIONS FOR EXCEPTION FROM INFORMED CONSENT REQUIREMENTS DESIGNED TO EVALUATE THE SAFETY AND EFFICACY OF POLY SFH-P INJECTION [POLYMERIZED HUMAN HEMOGLOBIN (PYRIDOXYLATED), POLYHEME] WHEN USED TO TREAT PATIENTS IN HEMORRHAGIC SHOCK FOLLOWING TRAUMATIC INJURIES BEGINNING IN THE PREHOSPITAL SETTING

I'm writing to summarize my contact with the Denver Fire Department in regards to the above-mentioned clinical trial.

To date, I have attended meetings at Denver fire stations 1, 4, 6, 19, 22 and 29, and have spoken personally with Fire Chief Roderick Juniel, Assistant Chief of Operations Kevin Caldwell, and Captain in charge of Emergency Medical Services, Brad Baulding. In addition, I have advised Mike Rodgers who is the President of the Fire Union. In all cases, secondary to time constraints, I spoke for approximately ten minutes underscoring what PolyHeme is, it's use, and how the trial will be conducted. Mike Rodgers offered to post information about the study on the Union's website, and to discuss the study at their next meeting. These presentations while informal, were very informative for all attendees.

Additionally, I have sent a brief summary to Captain Baulding, who will distribute this information to each firehouse.

As a final point, I have informed our Emergency Medical Services educators, who will be conducting mandatory in-services for the Denver Fire Department through the month of July and will include a brief summary of the PolyHeme trial at these in-services. This will ensure that every firefighter who works during the month of July will receive this information at least twice.



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While I believe that notifying this group was important, please keep in mind that even as first responders they will have no medical contact with potential study subjects beyond Basic Life Support, e.g. while they may perform first aid and potentially Cardiopulmonary Resuscitation (CPR) they will not start intravenous catheters (I.V.) or administer resuscitative fluids. Therefore, they will have essentially no impact on the subject's potential participation in the study. Furthermore, we believe that formalizing training for this group is unnecessary and likely impossible.

Please feel free to contact me, or study coordinator Jeff Long with questions or for additional information.

Sincerely,

Christopher B. Colwell, M.D.
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Attending Physician, Emergency Medicine
Medical Director, Denver Paramedic Div. and Denver Fire
Denver Health Medical Center