

MILTON S, HERSHEY
MEDICAL CENTER
HERSHEY, PA



DATE: February 8, 2005

TO: David Ungar, MD., Board B Chair

FROM: Robert A. Cherry, MD, Trauma Program Medical Director *rac*

RE: IRB Protocol No. 19815 – A 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), Polyhemea] When Used to Treat Patients in Hemorrhagic Shock Following Traumatic Injuries, Beginning in the Pre-hospital Setting

As per the Institutional Review Board (IRB) letter dated November 19, 2004 the following documentation of community consultation and public disclosure activities is being submitted for review for the application of the above referenced research. Copies of the following are included:

Part 1:

1. PolyHeme Website information – available on the Internet and HMC Infonet
2. Response card – placed in selected inpatient areas of HMC as well as selected locations of UPC and UPG clinics
3. Crescent article December 29, 2004
4. Campus Events and Activities Week of 1/2/05
5. Attendance record from HMC staff information meetings held January 4, 2005
6. Penn State Newswire Release January 5, 2005
7. Media packet given to members of press attending sessions on January 5, 2005 – Materials included Media Advisory, Exception from Informed Consent Requirement, PolyHeme Background, Questions and Answers, PolyHeme Trauma Trial presentation slides. In attendance were David Wenner from The Patriot News, WITF radio, WLBR radio, WHP-TV/Radio and ABC 27 (WHTM-TV)
8. Penn State Live article January 5, 2005
9. Media Advisory Announcing study
10. ABC News Channel 27 story
11. WGAL Channel 8 announcement (site has video clip as well)
12. The Patriot News article, January 6, 2005
13. Central Penn Business Journal article, January 6, 2005
14. The Innominate News, January 2005
15. FOX 43 News website link after interview
16. Medical + Buzz Health News website
17. Science Daily website
18. PSU The Graduate School article
19. The Sentinel (Cumberland county) newspaper article, January 7, 2005
20. LINCSS – online newsletter sent to 700 local churches
21. Cumberland County Commissioners meeting media advisory/public notice
22. The Sentinel (Cumberland county) newspaper article, January 11, 2005
23. KYW1060 News Radio release

24. The Daily Item (Northumberland/Snyder county) newspaper article, January 12, 2005
25. The Patriot News article, January 12, 2005
26. The Patriot News (Carlisle bureau) article, January 14, 2005
27. The Patriot News editorial, January 14, 2005
28. Dauphin County Commissioners meeting media advisory/public notice
29. Lebanon County Commissioners meeting media advisory/public notice
30. Lancaster County Commissioners meeting media advisory/public notice
31. Crescent article (page 2) January 19, 2004
32. Letter to local and state Congress officials with accompanying list of names
33. Response letter from Senator Jeffrey Piccola
34. Lancaster Intelligencer Journal (Lancaster county) January 26, 2005
35. Lebanon Daily News article, January 29, 2005
36. NewsTarget article, January 31, 2005
37. Letter that accompanies bracelet for those wanting to decline participation in study

Pending community education efforts at the time of this letter include:

1. Article in The Call newspaper (Schuylkill County) to appear February 16, 2005
2. Radio "spots" to be aired on local stations starting the week of February 14, 2005 targeting specific minority listeners
3. Presentation to the GI Clinical Management Conference group on February 16, 2005
4. Contacting a representative in the Lancaster County region to facilitate a discussion and awareness of the study for Amish individuals living in the area

Other presentations to hospital and community forums included a presentation to the COM Teams Council, Pastoral Care Services, Medical Advisory Committee of the Emergency Health Services Federation who serves as the regional oversight committee for EMS services in central Pennsylvania, and a presentation by Dr. Darrell Kirch to the Board of Directors. I also participated in a presentation for Black History Month by ABC 27 (WHTM-TV) on February 4, 2005.

WHP 580 Radio, in attendance at the media event on January 5, 2005, is a member of the Clear Channel radio group and broadcast reports about the study on their sister channels including:

1. KISS FM 99.3 – young listeners station target audience women primarily ages 18-34
2. WRVV 97.3 – target audience primarily adults ages 25-54
3. BOB 94.9 – country station target audience adults ages 25-54

Part 2:

The PolyHeme Trial website has yielded seven responses. Four declined participation due to religious convictions. The other three responses are included for your review in which two declined support for the study for various reasons. The third is in support of the study and had multiple questions about the product itself.

Part 3:

The online and response card survey yielded thirty-five (35) responses. The responses and accompanying comments are included. One responder omitted age in his response and four omitted ethnic background in their responses.

The phone number put in place specifically for study call-in response has thus far yielded eleven (11) phone calls in which individuals left messages or the call was answered by the clinical research coordinator at the time it was placed. Two individuals requested bracelets to "opt out" of the study citing health and allergy related reasons. Two calls were from Jehovah's Witnesses. The other seven calls were from individuals asking questions about the product or verifying county commissioner meetings citing support for the study.

As per the printed material from the PolyHeme Trial website found in Part I of this documentation, meetings were held in Perry, Cumberland, Dauphin, Lancaster, and Lebanon counties. Ms. Kathleen Hay, PhD, CIP accompanied study team members to each meeting. Multiple attempts were made via the phone, fax and email over a six-week period of time to schedule a meeting with Schuylkill County Board of Commissioners. At this present time they have not responded to our repeated attempts to confirm a meeting date.

Communications with four African-American church congregations in Harrisburg resulted in response from only one. Study-related information was faxed per their request but they declined the offer for a formal presentation to their members.

On January 26, 2005 study members met with Philip Mitchell, Hospital Liaison Committee member for Jehovah's Witnesses of Central Pennsylvania Area and two other representatives of the committee as well. We discussed the church's position with regards to PolyHeme and the study. Based on exclusion criteria, Jehovah's Witnesses will not be considered for participation in the study. Durable Power of Attorney (DPA) cards, study bracelets, and medic alert bracelets were discussed as means to identify church members. During training of EMS staff, particular care will be taken to discuss ways of identifying Jehovah's Witnesses at the scene.



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DATE: February 21, 2005

TO: David Ungar, MD., Board B Chair

FROM: Robert A. Cherry, MD, Trauma Program Medical Director

RE: IRB Protocol No. 19815 – A 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), Polyhemea] When Used to Treat Patients in Hemorrhagic Shock Following Traumatic Injuries, Beginning in the Pre-hospital Setting

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This memo serves as a follow up to information submitted to the IRB for the above referenced study in preparation for the IRB meeting on February 21, 2005. The following items that were pending at the time of the submission are as follows:

1. Attached is the article that appeared Wednesday, February 16, 2005 in the Schuylkill county Citizen Standard newspaper.
2. Radio spots started broadcasting Monday, February 14th on WTCY 1400 AM, The Touch, a Harrisburg station targeting African-Americans. There will be a total of 153 spots over a three week period.
3. Presentation to the GI Clinical Management Conference group on February 16, 2005 was completed.
4. Terry Novchich, RN, CCRC, study coordinator, met with Kevin Splaine (HMC administration) on Thursday, February 17, 2005. Media packets were provided to Kevin who will contact two members of the Old Order Amish, members of the Council of Bishops. Once we have talked with them a decision will be made as how best to communicate with them about the study since they do not utilize television, newspaper, and radio.
5. Members from Northfield Laboratories will be at HMC on Tuesday, February 22, 2005 to complete interference studies with instrumentation that will be utilized during the course of the study.