

Salt Lake City, UT

Polyheme Blood Substitute Trauma Study

Frequently Asked Questions

News Release

Feedback Form

Division of General Surgery
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University of Utah

Polyheme® Blood Substitute Trauma Study

Information About the Study

Study Title: A Phase III, Randomized, Controlled, Open-Label Multicenter, 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

Exception from Informed Consent under 21 CFR 50.24 : This provision is made when patients are in a life-threatening situation requiring emergency medical intervention and currently available treatments are unsatisfactory. Participation in the study could provide a direct benefit to the patients enrolled in the form of survival, the risks are reasonable, and the research could not be conducted without an exception from informed consent regulations. Typically, patients who are severely injured and bleeding are unable to grant consent for treatment because of the nature and extent of injuries.

Study Purpose : To evaluate the life-saving potential of the PolyHeme® blood substitute when given to severely injured and bleeding patients, beginning at the scene of injury.

Principal Investigator : Stephen E. Morris, MD , Director of Trauma, University of Utah Health Sciences Center, Co-Director, Intermountain Burn Center, University of Utah Health Sciences Center

Contact Information : Lisa Reynolds, RN, BSN, Clinical Research Coordinator, Department of Surgery, University of Utah School of Medicine, (801) 585-0385, lisa.reynolds@hsc.utah.edu

Sponsor : Northfield Laboratories Inc., Evanston , Ill.

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Polyheme Blood Substitute Trauma Study

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News Release

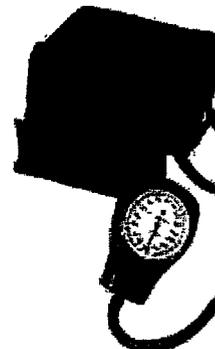
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Polyheme® Blood Substitute Trauma Study

Frequently Asked Questions and Answers



- Why is this study being conducted?
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- Will patients still receive treatment if they don't want to participate in the study?
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- What are the potential risks of PolyHeme® ?
- How much will it cost patients to participate?
- Will patients get paid to participate?
- Who is the manufacturer of PolyHeme® ?

Why is this study being conducted?

To evaluate the safety and efficacy of PolyHeme® in treating severely injured and bleeding patients, starting at the scene of injury, and to assess a potential survival benefit.

What is the title of this study?

A Phase III, Randomized, Controlled, Open-Label, Multicenter, Parallel Group Study With 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

What is PolyHeme® ?

PolyHeme® is a temporary oxygen-carrying red blood cell substitute made from human blood. PolyHeme® requires no cross-matching, and therefore is compatible with all blood types. PolyHeme® is manufactured using steps to reduce the risk of viral transmission. a shelf-life of over 12 months.

What is the design of this study?

Patients in "hemorrhagic shock" will begin to receive either saline (salt water), which is standard of care (control), or PolyHeme (investigational treatment). Treatment will begin before arrival at the hospital, either at the scene of the injury or in the ambulance, and continue during a 12 hour postinjury period in the hospital.

In the hospital, patients in the control group will receive saline for hydration and blood if necessary to boost oxygen levels. Unlimited doses of each are allowed.

Patients in the treatment group will receive saline (salt water) for hydration and PolyHeme to boost oxygen levels if necessary. The maximum dose of PolyHeme® will be 6 units the first 12 hours. Blood will be used thereafter, if necessary.

What is hemorrhagic shock?

A condition in which a patient has experienced massive blood loss.

Shock is a life-threatening condition that might include:

- *Dangerously low blood pressure*
- *Internal organs not receiving enough oxygen and have difficulty functioning, which could lead to death*

Why is there a need for improvement in the way trauma patients are treated now

Trauma is the leading cause of death among Americans under the age of 45. Currently only available treatment for hemorrhagic shock, when blood is not available, is the infusion of a solution that does not carry oxygen such as saline (salt water). Therefore, when blood is not immediately available, use of an oxygen carrier such as PolyHeme® may restore sufficient circulating levels of hemoglobin and potentially improve patient survival.

There are also risks associated with large infusions of donated blood in trauma patients including an increase in immune function which may cause failure of vital organs and in some patients who receive transfusions [A. Sauaia et al., Archives of Surgery (1994), 129:39-45]. In a controlled Phase II trial in hospitalized trauma patients, higher levels of immune markers were seen in patients receiving blood transfusions as opposed to those who received PolyHeme® [E. E. Moore, Journal of American College of Surgeons (2003), 107:196 (1)].

What is the current standard of care? How are trauma patients usually treated?

Bleeding patients are given a solution, such as saline, at the scene or in the ambulance to raise blood pressure. When patients arrive at the hospital, they are given Type O blood if needed immediately, and later receive cross-matched blood, when available, if they go to need blood transfusion.

Who is eligible for the study?

- *Patients who have lost a large amount of blood and are in shock*
- *Patients who are at least 18 years old*
- *Patients who have sustained severe injuries*

Who will be excluded from the study?

- *Women who are obviously pregnant*
- *Patients with severe brain injuries*
- *Patients who require CPR to maintain their heartbeat*
- *Patients with "unsurvivable" injuries*
- *Patients who are known to object to blood transfusions*
- *Patients who are known to refuse resuscitation*

How many patients will be enrolled in the study?

A total of 720 patients will be enrolled in the study; 360 patients in the control group and 360 patients in the PolyHeme[®] group.

Has enrollment begun anywhere?

Currently, enrollment is underway at a 17 Level I trauma centers across the United States. A list of those centers is available at www.clinicaltrials.gov. The FDA has approved the study as well as a total of 22 Institutional Review Boards. One IRB did not approve the study.

How will patient safety be assured in this trial?

An Independent Data Monitoring Committee, consisting of independent medical and statistical experts, is responsible for periodically evaluating the safety data from the trial and making recommendations relating to the continuation or modification of the trial protocol to minimize any risks to patients. The protocol includes four planned evaluations that occur at the first 60, 120, 250 and 500 patients have been enrolled and monitored for a 30-day follow-up period.

What has been the experience with the study since it has begun?

The Independent Data Monitoring Committee (IDMC) has reviewed the safety data on mortality and serious adverse events from the ongoing trauma study after the first 60, 120, and 250 patients were enrolled and followed for 30 days. After these three safety looks, the IDMC recommended that the study continue without any change. In addition, at the 500 patient look, the IDMC conducted an adaptive sample size determination as specified in the protocol. A blinded power analysis was performed to determine if any increase in the size of the study was necessary. The assessment was based on a comparison between the mortality rate predicted in the protocol and the observed mortality rate in the trial to date. The IDMC has concluded that no adjustment in the number of patients to be enrolled in the study is required.

How many units of PolyHeme[®] have been given to patients previously?

Northfield has experience with PolyHeme[®] in patients with acute blood loss in trauma or elective surgery in the hospital setting, including those who have received up to 20 units (pints) containing 1,000 gm of PolyHeme[®]. The normal volume of blood in a human is approximately 5 pints (units) containing 500 gm of hemoglobin. This means that up to two times the normal volume of blood in a human has been replaced by PolyHeme[®]. Some of these patients

kept alive while losing virtually all of their own blood during ongoing bleeding and received only PolyHeme® as replacement. Observations in these patients have suggested the life-sustaining potential of PolyHeme® in the treatment of urgent life-threatening blood loss and life-threatening hemoglobin levels [Gould et al, Journal of American College of Surgeons (2002), Volume 195 (4)].

What has been the safety experience with PolyHeme® in prior studies?

During the course of evaluation of any investigational product, both adverse experiences and serious adverse experiences can occur. These may be due to either the underlying condition of the patient, the treatment setting, or the investigational product itself. Both adverse experiences and serious adverse experiences have occurred in prior studies.

PolyHeme® was studied in one trial in patients experiencing planned acute blood loss during elective surgery for abdominal aortic aneurysm. The trial included a non-replacement procedure called acute normovolemic hemodilution (ANH) in which a large quantity of the patient's own blood, up to 60%, is removed prior to the surgery, and is later replaced. The procedure in this study resulted in the infusion of large volumes of blood in addition to 10 units of PolyHeme® in the experimental group, while smaller overall volumes of blood were administered in the control group. Serious cardiovascular adverse experiences occurred more frequently in the PolyHeme® group. The patients in this study were older with more cardiovascular risk factors than those in the trials in trauma patients. It cannot be determined whether these findings are due to the more extensive ANH in the PolyHeme® group, to the reinfusion of more blood following surgery in the PolyHeme® group or to PolyHeme® itself.

In trauma patients, PolyHeme® has been rapidly infused during urgent life-threatening blood loss in sufficiently large quantities, up to 20 units (pints), to be considered well-tolerated in this patient population [Gould et al, Journal of American College of Surgeons (2002), Volume 195 (4)].

What is an exception from informed consent?

Patients are enrolled in a clinical study without giving informed consent before being enrolled.

Why was such an exception granted in connection with this study?

Patients are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence is necessary to determine the safety and effectiveness of particular interventions.

Participating in the study has the potential for direct benefit to the enrolled patients, such as an increase in survival, because:

- *Patients are in a life-threatening situation that necessitates intervention*
- *Previous studies support the potential to provide a direct benefit to enrolled patients*
- *Risks associated with the use of the PolyHeme® are reasonable in relation to what is known about the patients' medical condition, the risks and benefits of standard therapy, and the risks and benefits of the proposed intervention*

It is expected that patients will be unable to give informed consent because the extent of their injuries and the fact that they are in shock.

It is unlikely that there will be time to find and ask for consent from the patient's legally authorized representative (LAR) or to provide an opportunity for a family member to object to the patient's enrollment before beginning treatment.

Who grants such exceptions?

The U.S. Food and Drug Administration (FDA) under regulations called 21 Code of Federal Regulations 50.24 specifies the conditions under which an exception from informed consent may be obtained. The Institutional Review Board (IRB) associated with each hospital approves its use locally.

What if I don't want to participate in this study?

Members of the public can object to participating in the study by wearing or displaying exclusion bracelet (offered by the clinical site or from the manufacturer). Patients enrolled in the study may withdraw from the study, without prejudice, at any time by notifying the investigator.

Will patients still receive treatment if they don't want to participate in the study?

Patients will still receive the standard of care if they decline to participate in this study.

What are the potential benefits of PolyHeme®?

- *PolyHeme® may increase the likelihood of survival after traumatic injury*
- *The need for blood transfusion might be reduced*
- *Patients might avoid a reduction in the function of internal organs that sometimes follows blood transfusion*

What are the potential risks of PolyHeme®?

- *Rash*
- *Increased blood pressure*
- *Kidney or liver damage*
- *Transmission of hepatitis and HIV viruses*
- *Unforeseen happenings*

How much will it cost patients to participate?

There is no charge to the patient to participate in this study. The costs of certain laboratory tests that are required will be paid by the study sponsor.

Will patients get paid to participate?

No, patients will not be paid to participate in this study.

Who is the manufacturer of PolyHeme®?

Northfield Laboratories Inc., Evanston, IL. For more information, visit www.northfieldlabs.com

"No Participation" Study Bracelets :

To obtain a bracelet to decline participation in the study, please contact: Lisa Reynolds Clinical Research Coordinator, University of Utah School of Medicine, Department of S 30 North 1900 East, 3B301 Salt Lake City, Utah 84132 801-585-0385 or lisa.reynolds@hsc.utah.edu

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3 mins

Transcript, Local Evening News, June 14th, 2005, 5:00 pm

ABC, Channel 4, 2 minutes:

Randall Carlisle, Anchor: What if you were a trauma patient and needed blood? Paramedics will actually be using a synthetic blood on trauma patients but there is a catch; you can't agree to use it if you are unconscious. ABC 4's Heidi Hatch shows us what this product is and when will be used, Heidi...

Heidi Hatch, Reporter: If I were involved in an accident and was a trauma one patient and was losing a lot of blood the only option paramedics would have for me at this point is using saline to keep something flowing through my body and get that fluid moving. But now there is another option with this new study. They can give me hemoglobin. This would get the oxygen flowing to my brain and other organs until I could get to a hospital to receive blood.

Stephen Morris, MD: When a patient is bleeding to death, we are limited to just giving them salt water, saline.

Hatch: Blood cannot be transported to the accident scene for a myriad of reasons and without enough, the brain and internal organs are deprived of oxygen and that's how most trauma patients die.

Morris: We are looking at patients who have lost so much blood that they are going into shock.

Hatch: Paramedics now have another option. It is called PolyHeme, a synthetic blood made from hemoglobin.

Morris: It is something that is compatible to all patients, no matter what the blood type, and can be transported right to the scene. A synthetic blood product is something we have been waiting for years to show up on the scene.

Hatch: In the past, attempts at such a product have been made but this caused organ damage or failure. PolyHeme is in its third phase of FDA trial with the only side effects being possible rash or high blood pressure.

Morris: Will this help to save lives? We don't know that it will.

Hatch: But trauma teams at LDS and University Hospital want to know. That's why they, along with teams from West Valley, Sandy and Salt Lake City are participating. That is, if the community agrees to the study.

Chief Van Summers, West Valley Fire Department: I can tell you that I have had many patients that we've taken into the hospital setting and they weren't able

to survive because we weren't able to give them a product that had oxygen carrying capability.

Hatch: Most trauma patients are unconscious and could not make the decision at the time to participate in the study. For that reason, they want to have everyone understand what it does. If you don't want participation, call the hospital and get a tag like this. You can wear it on your wrist or hang it in the windshield of your car so paramedics will know when they come to the accident scene that you do not want the hemoglobin. Back to you.

Carlisle: All right, thank you Heidi. In the next few weeks there will be community comment meetings and a chance to voice your opinion. If the feedback is positive, the study will go forward. For information you can go to our website and ABC4dotTV.

Transcript, Local Evening News, June 14th, 2005, 6:00 pm
NBC, Channel 5, 3 minutes:

Bruce Lindsay, Anchor: Hundreds of patients lives may be saved using a synthetic blood project on critically injured patients.

Dene Wimmer, Co-Anchor: Who will be most likely to give the first new transfusions? Ed Yates joins us now, live.

Ed Yates, Science Reporter: Dene, we are talking about first responders, those trauma teams that arrive at the scene of the accident. These are the folks that will most likely be giving this synthetic blood to patients, first. Since there isn't enough time to transport real, whole blood to of an accident scene for transfusion, the treatment for now has been simple but often ineffective.

Stephen Morris, Director of Trauma Services, University of Utah: When a patient is bleeding to death, we are limited to just giving them salt water, saline.

Yates: But this synthetic blood product called PolyHeme can be carried in ambulances, rescue units, emergency helicopters like AirMed or Life Flight and given immediately on location to anyone, regardless of their blood type.

Morris: PolyHeme is actually a solution of hemoglobin which is the oxygen carrying part of our blood.

Yates: This compound now carries oxygen to the brain and other vital organs even though your own blood is dwindling. The FDA wants to know if in all these emergency situations, PolyHeme will in fact increase your chances of survival. So, a national clinical trial is proposed involving 20 medical centers including LDS and the University of Utah Hospitals and emergency trauma teams in Salt Lake County, Sandy and West Valley. This is a most unusual study because in most cases the patient will be in no condition to say yeah or nay to the study. So the advice, get one of these bracelets, "I decline the Northfield PolyHeme Study." Put in on your wrist or hang it in your vehicle. If emergency responders see this bracelet, they will NOT administer the PolyHeme. But so far, during Phase I and II Clinical Trials, the data on this stuff looks extremely promising.

Chief Van Summers, West Valley Fire Department: This synthetic blood product is something we have been waiting for years to show up on the scene.

Yates: If you need more information on these clinical trials or would even like to voice your opinion in writing or in upcoming community meetings about the unusual nature of the study, visit our website at KSLdotcom to find out more information.

Lindsay: All right. Very interesting, Ed. Thank you.

Transcript

PolyHeme Community Meeting, June 30, 2005

University Hospital, Classroom B, 4:30 pm - 6:00 pm

Lisa Reynolds, Introduction: I would like to thank everyone for coming; we'll get started. Dr. Morris is on his way and will be here momentarily. I am Lisa Reynolds, the Coordinator for the trial. I have been working on the study, to get it to this point, that we can present it to the community, for about six months. It is a complicated process. This is the fourth community meeting. Our guest speakers today are Stephen Morris, MD, who is the Director of Trauma Services for the Department of Surgery and this is Tonya Edvalson, representative from the Institutional Review Board. The Institutional Review Board, for those of you who don't know is the ethics board and to do research in this country, there are regulations we must follow when working with human subjects. This particular study has it's own set of special issues and Tonya is here to explain that I'll turn the time over to her.

Tonya Edvalson, IRB Representative: I just wanted to talk briefly about how the review process goes so you will understand the depth of review that does go on in these studies. We've only had one other study like this at the University since I've been here for 6 years and it was the Defibrillator's that you are now seeing against the walls in the malls and at the airport. That happened about three years after the regulation came into play so it was really new to us then. It takes so much longer than you realize. You really have to look at the interpolation carefully.

So what our boards are made up of: Physicians multiple disciplines. We try to match the types of studies that are coming in with a natural representation from those departments as possible. We have PhD level, they can be biochemists,

they can be social scientists. They are also on the panel not only to just review those types of studies, or the, what we call our main campus behavioral sciences studies but there are a lot of things that come through and medical studies have social impacts also so we rely on them to kind of think about what could happen from a psychological or social standing on that. The other member we have, we also have people who are non affiliated. They have nothing to do with the University; they are not married to anybody at the U, they don't work at the U, haven't retired from the U usually. We look at people really carefully to make sure that they're coming from an outside perspective, so they can say to us, "Wait a minute, you guys are a little bit too caught up in your own little world, we need to talk about this." And then we also have, representatives from Primary Children's Hospital and the VA as well. The other group that I think is the most important group on our panel is: not that the MD's are not important, but the community representatives, they are the non-scientists, people that are going to be driving their cars down the road, the ones that are going need a Doctor and need to be administered these drugs. So they're the ones we rely on to come in and tell us that, "Hey, you are making this too complicated for the regular person to be able to read consents or even understand what's going on." So we rely on them quite a bit and each panel has about two or three members, not a big proportion but they are very vocal and are great to have on the panel.. So what they do, at least in our office, when this study was submitted, I think it was in February initially, it undergoes a pretty extensive review in the office just administratively to make sure we have what we need to send it to a board meeting. And then, based on when it's submitted and who is available, sometimes based on a study, we assign it to one of the four panels at the University of Utah. We have four panels, one of which meets every week, and they are made up of different people. We have about ninety, ninety-eight or one-hundred people committee members right now. So there's a lot of different people. This one ended up with Panel One and they reviewed it in the first week of March and when we reviewed that study, the science seemed to be sound, everybody wasn't as concerned with the risks, they felt like everything had been

in compliance with monitoring and safety data but they were very concerned about the community and this exception from informed consent. One of the things they worry most about was that people understand what they are getting into. So most studies that the FDA puts through, you've got the person in the clinic sitting in front of you, and you can say, "OK, you now have this infection we know about, this is what has worked in the past, this is why we are trying something new, these are the procedures we are going to do while you are in the study. These are the risks, the benefits", all those kinds of things. So it's an ongoing dialog with the participant. But when you are out on the road and in shock, that is not an option and even if they are awake and aware of what is going on, they may not be in the right frame of mind to give consent as well as your family members who might be there as well. So one of the things they do is have regulations in place and they aren't used very often, that do allow for that exception from informed consent. So, this strict phase that was sent to Dr. Morris and to Lisa early on in the process to say, "how are you going to meet this for us?" Please define these things, help us to know what you are going to do." So, that first meeting, we didn't have exactly everything we wanted so we weren't comfortable saying we were ready to approve it. So it was tabled and then it went to the meeting back in April. So at that meeting they reviewed everything that had been submitted to us: The Community Consultation Plan, there are some parts here about response persons that we'll talk about here a little bit further, basically how people are going to decline, how are we going to get people these arm bands to wear or put in the car, so that people who really do object can have the opportunity to voice their opinion. Now that that is place, we aren't quite ready yet. We need to see what the reaction is from the community. Is Salt Lake City really ready for something like this. What IRBs really have to do is look at the community representation as well. There are some communities that won't fly with this and we're just making sure that everybody is as comfortable as possible in the sense. Once we approve it, we have a lot of ongoing monitoring. If there is a side effect in this study; expected, serious, anything like that, they have to report that to us and we have to be able to look at

that. If there is a death in the study it's immediately reported to our office so that we can try to look at what the cause was. If we think that it's at all possibly due to the drug, we may stop the study, and say, "we need some time to evaluate this and see whether or not we want to keep going." They also have committees on their side looking at the safety data from all the centers, Utah as well as everybody else. And then we are asking them to report to us on a quarterly basis, saying how many people are involved, how many people got the drug, how many people are going great, what kind of things happened. How many people we actually got consent from; authorized representative, how many we got from the patient after they came out of it. Those kind of things they will tell us. There is also a requirement that if someone actually gets this PolyHeme and half of them will, that they do have to notify the family.

Every year at least we do a full review with a big application, a full board review. So the way the boards look at this, is we assign it to, with this particular study we assigned it to a MD, so a physician and also a very experienced board member on our panel, she is a PhD and she has been on the board for a long time so we know she understands issues. She was involved with the first study that had this. So we rely on them a lot but we also have, oh, twenty other people in the room who have the same information. Most of the information they have and they also have their input, so, the board in review, they have a lot of discussion about it but in the end, we have to have a simple majority of people in the room to vote. On this study, I looked it up before we came over here, we had seventeen people approve and one person abstained.

We are here to help the participants, We're also here to help Lisa and Dr. Morris but our primary concerns are the people who are going to be getting the infusion and their safety. So, working together as well as we have makes that more possible. I think that we have an understanding of what is going on in the study and how everybody is going to work together. That is our primary concern and anytime anybody is concerned about it, they can call them but they can also call our office as well. I'll leave cards down here in case anyone wants to call.... If

there are other questions about the review process. But, I'll let Dr. Morris go next because he has lot of good information. Then we'll be here after in case there are questions.

Dr. Morris, Principal Investigator, Director of Trauma: "You can keep talking for a minute longer".

Audience question for Tonya: "So does your IRB exclude LDS Hospital"?

Tonya: As far as I understand, and we have representatives from LDSH, it was submitted today. Discussion between LDS representatives and questioner, inaudible.

Question continues: So my concern is that if we start this project within the next month or two, what is their involvement?

Tonya: They won't have any involvement until their IRB has approved it.

LDS IRB Representative: We'll be reviewing that study on July 14th.

Question continues: How long does it take to get that though LDS?

LDS IRB Representative: It depends on the committee, it just depends on what they say. It could be approved on July 14th or they may other questions. We hope to have Dr. Lazarus there with information for the study.

Tonya: We're on our fourth month here.

Question continues: Well that's what I'm concerned about. Is their involvement with the study going to delay thing for us?"

Tonya: They are really separate. They are responsible for their own pocket of stuff and monitoring, that becomes solely their responsibility.

Question continues: I am just so concerned that it will delay for us and I don't want to be any more delayed at University of Utah.

Tonya: If Life Flight lands on scene, they won't even have the drug.

Dr. Morris: Just to make it clear, ah, we are not yet approved to enroll patients at the University. The community consultation process, because of the nature of the study, it's very important because that's basically the informed consent process and we need to be careful with this informed consent. So, we cannot begin to enroll patients until our IRB has made approval. Now, LDS Hospital has a separate IRB so the hospital will not be able to join unless approved to do so. Each individual pre-hospital agency does not require IRB approval. Life Flight, Air Med, Sandy, West Valley, Unified which is County, and City can work under our IRB but I don't know if LDS Hospital as a corporate structure would bar Life Flight from any participation because they have their IRB. I do not know that.

LDS IRB Representative: That's a great question, I'll find out.

Dr. Morris: Let's get started. I'm Steve Morris. I apologize, I had two meetings scheduled at the same time and tried to divide myself between the two. I am the PI here and we were approached by Northfield, who is the sponsor of the study approximately 18 months ago and it has taken us quite a bit of time to get our infrastructure in place to be able to do this properly. It is well identified that trauma is one of the major causes of death in the United States and in fact is the number one cause of death in people under the age of 45. And, certainly thousands if not tens of thousands of people die every year from traumatic causes. In those traumatic causes, blood loss is a big one, A lot of people die from exsanguination at the scene. A lot of people die en route to trauma centers and in the hospital because of exsanguination. The standard of care at this point is saline or some salt solution given IV as soon as hypovolemia is identified as a problem. As blood loss becomes an issue, we have saline solution available in the trucks and on helicopters at the scene and that is begun. Now, that solves one of the problems and that is lack of fluid to pump around to supply blood to

the brain and the heart and other organs of the body. But it doesn't replace oxygen carrying capacity which is in the red blood cells of the blood and, so, since Vietnam, there has been a quest not only in the United States but also the developed world to find substitute blood. There have been various councils looking at other types of substances. There have been some major studies that were started and found to be deleterious to patients so there was a lot of regrouping since the mid-80s to early 90s. So, since that time, hemoglobin has been identified as a probable carrier of oxygen and how that hemoglobin is given to patients has been a point of research. So, Northfield has been working on this for the past 30 years and about over the past decade, they have looked at this substance called PolyHeme which is hemoglobin from humans, from human blood which is outdated that is then purified, polymerized somewhat, not as much as it was in the previous preparations. There are about four units of hemoglobin, very similar to the hemoglobin structure in our own blood stream. And, a, then it's chemically adjusted with Vitamin B6, Pyridoxine that is then attached to this to allow it to absorb oxygen and release oxygen, in a very similar manner to the way it does in our own red blood cells. This hemoglobin is in a solution. It's not packaged in little red blood cells but PolyHeme is packaged in 500 mL, that is a one pint bag, very much looking like a unit of blood. That contains 50 gms of hemoglobin, very similar to a unit of blood. There are some advantages to PolyHeme over blood. Number 1, it has a shelf life that is much longer. Blood can be taken out of the blood bank and put in a cooler and within two hours it can no longer be returned to the blood bank, even on ice. Whereas, PolyHeme, within that same system, can be stored for a year. As long as the cooler is maintained properly, the coolant is replaced once a day, it can last for up to one year. And, so, it's got a better shelf life. The other thing, even though blood is a pretty safe product, extremely safe, now, as related to viral substances such as Hepatitis, HIV... it still could be improved upon. All of the safeguards are performed on PolyHeme and then it is processed and purified a little bit more. So, the risk of HIV is thought to be even lower with PolyHeme. And, a, It is less viscous, and it can be more available. So the thought is that there can be an off

the shelf, easily storable substitute for blood that could be at the scene of injury instead of waiting until the patient gets to the hospital.

And so, that is where we were starting with PolyHeme. Now, the question is, what have we done so far to ensure safety and look at efficacy and beneficial effects. Phase one studies and phase two studies have been done of the last ten years. One study looked at trauma patients in the hospital that were losing blood and receiving PolyHeme and those did show a beneficial effect. That was reported in 2002, 2003. We are now at a point where we can do a large, multi-center, randomized study, looking at patients who are losing blood rapidly, that is, they are hemorrhaging and to the point that they are in shock, that means there is not enough circulation going to the brain, the heart, the liver and other organs of the body. And, so they are in this hemorrhagic shock that is a lethal disease that kills thousands of people. In that population of patients, we want to see if giving PolyHeme early enough will affect their survival. So, the outcome variable for this study is: Do patients who receive PolyHeme survive in a higher proportion than patients who get the standard treatment which is just saline. And, so, this study has been up and running actually, in some centers since January 2004. Because of the concerns with previous studies, an Independent Data Monitoring Committee, was appointed that is has, if course, no real connection with Northfield nor with whatever happens with PolyHeme. They have looked at patients as they are accruing, looking at the data, looking at survival, looking at potential side effects and they have looked at the point of where 60 patients have been enrolled, 120 patients have been enrolled, 250 patients have been enrolled and we are somewhere between 250 and 500 patients. At each one of those time points, the IDMC review committee found that there was no increased risk for adverse events with PolyHeme as compared to saline. And, it looked like we would be able to answer the question is PolyHeme beneficial compared to standard treatment with saline by the time we get to 720 patients, nationwide. They recommended that this study continue. At this point in time, we are somewhere, say between 250 and 500 patients.

So, the study at this point in time is enrolling at 20 centers in the US. Centers such as USD, Scripps, Denver General, Metro in Cleveland, Baltimore. You can actually look at www.clinicaltrials.gov to see centers who are currently enrolling. There are 22 centers now that have been approved by IRB and there has been one center in Boston that the IRB denied the application, feeling that standard treatment was perfectly adequate. We tend to disagree and I think our IRB must disagree also because they feel that this is a question that needs to be answered. It's not that any of us know that PolyHeme is any better but we would certainly like to contribute to finding the answer.

There is a website we have that will give you information from our perspective. Northfield is the sponsor of the study and they have an extensive website that will give you more information.

So, here is the question: To evaluate the life sustaining potential of PolyHeme when given to patients who have hemorrhagic shock, they are bleeding to death, beginning at the scene, outside the hospital. That is how this study varies from all the other studies that have been performed with PolyHeme. Hemorrhagic shock is a potentially lethal problem. We talked about conventional treatments, at this point in time, saline solution outside the hospital and blood as appropriate when in the hospital. But we know there is a problem with saline. Blood in and of itself does have risks. There are viral infections issues, however low. Another one is the body's response to blood. We certainly do know that blood carries a lot of antigens that helps one person tell the difference from another person, the immune response to the blood compatibility antigens. We do know that, also, somewhere among all those antigens, that giving blood to patients, both trauma and non-trauma patients stimulates the immune system and this stimulus is usually quite detrimental and can lead to organ dysfunction, lung problems we call pulmonary edema or acute respiratory distress syndrome, (ARDS), liver problems, GI and gut problems all associated to inflammation. PolyHeme has a decreased inflammatory response compared to the administration of banked blood.

That is a picture of PolyHeme. It looks like blood because it does have hemoglobin. We talked about all of that, and we talked about some of the potential benefits. We want in this study to look at the use of PolyHeme in the first 12 hours, that is, we certainly feel that if we do something differently in the first 12 hours, giving PolyHeme early and aggressively that there is a potential for benefit as opposed to saline. .

There is the real question, to evaluate the potential improvement and survival of severely injured and bleeding patients in the pre-hospital setting.

We do know that patients who do receive huge amounts of PolyHeme, up to 20 units, can survive. That is two blood volumes, because we all carry about 10 units of blood in our blood stream. Patients who have received 20 units of PolyHeme in the past have survived and had they not received either blood or PolyHeme, they would have died. So it does suggest there is a life-sustaining potential with PolyHeme.

As with blood, patients who receive PolyHeme don't all survive. Adverse events have been known in this population. The IDMC for this particular study knows there are a number of reasons the patient who received PolyHeme had adverse events. There may be other reasons. It could be the patient was very sick, cardiac problems due to age, etc. It could be the way the patient was taken care of. Were there surgical delays? Was the bleeding not controlled? Or, it could be the PolyHeme. The review board decided they could not distinguish between the three but somewhere among the three the adverse event arose and it was unclear as to the cause. For this case, the IDMC could not rule out that the PolyHeme did not contribute to the adverse outcome. We do certainly know that PolyHeme did not have as association with increased events and that patients lives could be sustained with this hemoglobin. In this randomized study, patients will receive only up to six units of PolyHeme.

The design is: nationally, 720 patients will be enrolled, half of whom, 360, will receive PolyHeme and half standard of care. You can look at this website to see all of the centers. The FDA did approve the study. They feel that this is valid and appropriate study. These are the time points I mentioned before, 60, 120, 250 and there will be another one at 500. It will run through calendar year 2006 and into 2007. So, we tentatively will be participating for a year to year and a half. As I mentioned before, the IDMC recommended that study continue.

So, patients will either receive control or PolyHeme. That will be decided not by the crew arriving at the scene but by the randomization protocol found out by opening the envelope once the patient is identified as a candidate for the study. Patients with traumatic injuries, they are in hemorrhagic shock. They will open an envelope at the scene and will either be in the control group or will be in the PolyHeme group. Our decision process is made in a random manner beforehand and no decisions are made to which group they will be in. This is just a graphic to show saline solution or PolyHeme. Once at the hospital, the PolyHeme, or test group will continue to receive PolyHeme for up to 12 hours.

Who is actually going to be a candidate for this study? A trauma patient. Someone who have lost enough blood to be in shock. They have to be adults. Children are excluded from the study. Pregnant females are excluded from the study as they are considered vulnerable. Others excluded, severely head injured because they die for other reasons. Also, patients who are so far gone that we don't have a realistic reason to believe that whatever we do will be effective. As part and parcel to that, patients who are actively undergoing CPR are excluded. They are probably unlikely to have any benefits so they are excluded. The other group is the group who do not want to receive blood or do not want to be in the PolyHeme study. Certainly patients who don't want to be in the study can't be in the study. Any way they can communicate that to us and there are several ways: Writing in, emailing us, send in a post card, call us, wearing a band that says "I do not want to be in the Northfield PolyHeme Study," or having said that to family members that can communicate that to us, they won't. OK, so, how are

patients protected when they can't tell us, we can't tell them about the study. One way is the FDA, that monitors this very carefully and makes sure this is being done in an appropriate manner. The FDA reviewed the study design, reviewed the manufacturing process, reviewed the scientific data to this point and they felt this is a study should go forward and not only should go forward but it should go forward with exception from informed consent. That means that there is a prescribed process in which the study can be done without obtaining consent from an individual before they are enrolled in the study. That is, ah, usually is, as I'm sure most all of you know, when patients are in a research study, the two treatments are described to the particular patient before they ever enter the study. Now, there are some studies in which we know it's going to be very difficult to do that and an unconscious and bleeding patient is one of them. Certainly when we are not able to do this and the patient is not able to choose, there has to be a way to protect the patient's rights concerning enrolling a patient into a study. And there is a way, it's called *exception from informed consent* and this is something the IRB is very expert at dealing with. There have been two in the intermountain area. I'm aware of the automatic defibrillators that are in the airports and downtown and at sporting event areas. That was an investigational device not too long ago and you know, when a patient is having a cardiac arrest and is unconscious, it's very hard to enroll them with informed consent. So, exception to informed consent was used. In 1996, the 21 CFR 59.24 created a process in which a study can be performed without prior authorization and there are a number of criteria that need to be met. One is, that this has to be a life threatening problem. It can't be, just discomfort, or cosmetic. It has to be something that effects their life. 2. That the present treatment is not satisfactory and that is where that one IRB disagreed with the 22 other IRB's. They felt it that it was satisfactory but I think the general opinion is that current treatment of hemorrhagic shock, pre-hospital is not satisfactory. That patients really are unable to give consent and also the last criteria that potential risk of the treatment protocol is acceptable, that those risks are reasonably small. Likewise, ah, the requirement is that participation in the research could be of direct benefit to that

particular patient. That means, if you are enrolled in the study and you get the study treatment PolyHeme, that could potentially you directly, and that certainly that the research could not practicably be carried out with the exception from informed consent. The FDA felt that this particular study filled all of those requirements and I think the IRB feels the same way. So, that does not exempt as a research organization from still trying to obtain consent. So, if the patient is talking to us at the scene, we will get at least verbal consent right there. If they are unable to, we will seek the legally authorized representative of that patient and talk to them about that, and certainly if possible we will get consent before enrollment. If not, we will continue to try to talk to the patient and to the legally authorized representative for that patient and try to obtain consent. If they want, the patient or family members wish to, the patient will be immediately withdrawn from the study.

Lets talk about risks and benefits. Certainly we know that PolyHeme can enhance the amount of oxygen in the patients blood. If that is lost, saline doesn't replace it, PolyHeme does. It may avoid the failure of vital organs because of oxygen transport or because of the inflammation that is associated with blood that is not associated with PolyHeme. It's possible that patients can live at a higher likelihood. We do know that PolyHeme, because it doesn't have blood type antigens is compatible with all blood types, is immediately available and concerning storage issues is much more convenient. And, it is commonly held that PolyHeme probably has a lower or sub-lower chance of transmitting any viral diseases from blood to the patient. Now, it doesn't mean that it's perfect. That's one thing we are trying to look at. There can be adverse effects. As with blood, patients can still develop a rash, can experience elevated blood pressure, could be kidney or liver damage, could potentially get infections from hepatitis or HIV. And it's possible that even something we don't know about could happen, but that being said, we feel that those risks are relatively small compared to potentially large benefits that could be derived from using hemoglobin solution like PolyHeme before the patient arrives at the hospital. Other protections; a

very important one is the IRB. We've talked a little bit about that already today and they are medical scientific community representatives that get together and ethically talk about whether this should be done, if it the right thing to be done. The review.... all proposals, I understand there are 2,000 in active proposals or applications that are reviewed or are ongoing right now, they are very busy. There are four board of the IRB right now reviewing studies. Patient safety is a very important part of their job, it ensures that all research done on human subjects is safe. And. it is responsible that that information is fed back into the community because they are representing the interests of every member, every citizen. The IRB first decides, they are the organization that has given us permission to even come to you to talk about this study and will continue to be really our boss as far as what we can or can't do as far as the study is concerned. They have not given authorization to begin enrolling patients into the study but certainly have allowed us to get to this point. In addition to the IRB, the IDMC that I talked about will continue to look at patient data that is submitted and a third very important safety measure is the FDA is continuing to monitor what is going on with the study. And, lastly, you as citizens, as members of the community will be able to get information back as to how the trial is being done, you'll know when its completed, what the results are and also, each individual member of the community can decide whether or not they individually want to participate or not. So, I think in summary, there are a lot of potential benefits from PolyHeme. I believe that this a well constructed study. That's why we decided to, to join in this effort. I believe that it's a real opportunity for us, as a community in the Salt Lake City area to participate in advancing care that could potentially benefit ourselves individually, as well as our children and our family members. Are there any questions about this?

Question: The entire process from an ethical point of view, you have a federal regulation that says you have to perform these certain criteria and one of the criteria was is there available satisfactory treatment.

Dr. Morris: Yes...

Question continues: Now, you said that your opinion, in the pre-hospital arena, you are not satisfied with treatment options and you would like to be able to give a blood substitute like PolyHeme.

Dr. Morris: Yes

Question continues: Now, your study runs for 12 hours and I would predict that in Salt Lake City, a patient would get to the hospital in the first hour. So, of a 12 hour study, one hour is in the pre-hospital arena and eleven hours are in the hospital.

Dr. Morris: That would be true right here in the valley but there are times, even in the valley that it takes longer, up to 6 hours to get a patient to the hospital. But you are right.

Question continues: So, the majority of the treatment time is the hospital, and in the hospital there is a satisfactory treatment option which is blood, because that's the standard of care. So you are now taking a citizen, such as myself, without informed consent, and depriving me of the option of having a satisfactory treatment in the hospital setting for the majority of your study period. How does that satisfy the requirements of the federal regulation?

Dr. Morris: Well, certainly I think that we know there are problems with blood. We know that blood has deleterious effects that PolyHeme may be able to circumvent. We also know that there are many patients who may not be able to get here in a reasonable amount of time and they would be deprived of that "golden hour" of treatment; from the time of injury from the time of getting to the hospital. That is the most important. If we deprive them of an oxygen carrying substitute for an hour or two or three, and then give them blood, than the "horse may already be out of the barn" at that point of time. And, the real effect on survival may not be able to be compensated for by blood in the hospital. So what we are doing is extending that potentially life sustaining treatment right out to where the patient is injured, rather than waiting. So, yes, I think that you have a

point in that, well, do you want to re-design the study so that they are getting blood as soon as possible. It may totally pollute the patient group so that we can't tell the difference and, yet patients will still be dying outside the hospital, or will be dying because of denying them a potential life-saving modality outside the hospital. And so, that is why I think the 12 hours was decided. At that point, hopefully surgical correction of hemorrhage will be taken care of and that the patients will still be able to have this life-saving modality. So, that really makes sense to me why they wanted to have a defined time period rather than a geographical location for PolyHeme.

Question: My question is did the sponsor actually try to do the study in a setting where the time is predicate, that average time from motor vehicle accident to the hospital would actually be longer? Because, number one, if they did that, than the chances of showing a benefit are greater and of course patients will benefit. Now, obviously not a practical one, but time predicted should be greater.

Dr. Morris: I think that's true. That would be a reasonable design to go to hospitals where there is a predictably longer interval from injury to definitive treatment. One of the problems there is, many of those hospitals do not have modalities of a level one trauma center. They would probably be level two or three or undesignated trauma centers. I think they wanted to take the standard of treatment, that level of care out of the equation and I think that's one reason they have been patient with us in being so slow to get ready for the study. We are probably one of the longest centers, centers with the he longest times from definitive treatment to standard of care in all of those groups. Certainly, Denver General has a shorter interval than we do, Scripps has a shorter interval that we do. Thinking of those other centers, they probably are more urban than we are although we have a large amount of urban care, I think we still have a long interval from injury to standard of care. But that would be an interesting study to pursue, in patients who have a very long transport time and interval from injury to

definitive care is the effect of PolyHeme even greater than having this one hour time we were talking about. Any other questions?

Question: How many people are you expecting in this trial?

Dr. Morris: On yes, we applied for 36 over 12 months. We feel that we probably have candidates for twice that, but from a practical standpoint, we feel that we can probably enroll at each center 20, to, up to 36 patients. Well, thank you for bearing with us. Oh, question.....

Question: I have a lot of questions but came in late and you may have covered it. So if I may talk with you afterwards.....

Dr. Morris: If you would like to come down, we can discuss it privately, sure. If there is something you would like to discuss in public, we have great levels of expertise here.

Question: Is this study 6 units or 12 hours?

Dr. Morris: Yes, whichever comes first. Patients cannot receive more than 6 units and cannot receive it beyond 12 hours from the time of injury. I can't imagine they would get 6 units but it may happen.

Question: I am from the OR, will there be education?

Dr. Morris: That is a very important item you bring up, and that is a large amount of education within all areas of hospital personnel, the ER, OR, etc. There is an elaborate education system with modules for each audience that will have to be completed before we enroll our first patient. But, we have to get the study approved to enroll first. It's done in steps. We anticipate and maybe it's a little optimistic but we anticipate it will probably take until September, somewhere around there before everyone is educated and we are able to enroll our first patient. Thank you very much.

From: Stephen Morris
Date: 5/9/05 10:11:11 AM
Subject: PolyHeme® Trauma Trial

Dear Colleagues,

University Hospital has been chosen for participation in a national clinical trial to test a new synthetic blood product in the treatment of trauma patients. We are one of 20 major trauma centers in the United States, and the only Level One Trauma Center in Utah expected to participate in the one year study. The study will evaluate the safety and efficacy of PolyHeme®, a hemoglobin-based, oxygen carrying blood substitute, to increase survival of critically injured and bleeding patients whose injuries resulted from blunt force or penetrating trauma. The product under study is called PolyHeme®, an investigational, temporary oxygen-carrying red blood cell substitute. The substance is universally compatible and immediately available; treatment begins before arrival at the hospital, either at the scene of injury or in the ambulance, and continues through a 12-hour post injury period in the hospital.

Patients enrolled in the PolyHeme® study will impact many departments within the hospital. Thus, we have scheduled an informational meeting with representatives of the study sponsor, Northfield Laboratories of Chicago, IL., and representatives from the ER, OR, AirMed, SICU, Anesthesia, ARUP and EMS agencies in the community, and would like to invite your participation. The meeting will be Friday, May 27th at 07:00 am, in Classroom C and will last approximately one hour.

This is an important meeting to attend in order for this study to get up and running. If you are unable to attend we would appreciate you sending a representative in your place. Please RSVP to the trauma research nurse, Lisa Reynolds, at 585-0385 or lisa.reynolds@hsc.utah.edu.

I thank you in advance for your support in this matter. Please let me know if you have any questions.

Sincerely,
Stephen E. Morris, MD
Director, Trauma Services
University of Utah

From: Stephen Morris
Date: 5/9/05 1:08:10 PM
Subject: PolyHeme® Trauma Trial

Dear Colleagues,

As you are aware, University Hospital has been chosen for participation in a national clinical trial to test a new synthetic blood product in the treatment of trauma patients. We are one of 20 major trauma centers in the United States, and the only Level One Trauma Center in Utah to participate in the trial. The product under study is called PolyHeme®, an investigational red blood cell substitute.

We have scheduled an informational meeting with representatives of the study sponsor, Northfield Laboratories of Chicago, IL., and would like to invite your participation. The meeting will be Friday, May 27th at 09:00 am, in Classroom C and will last approximately one hour.

This is an important meeting and we hope you will be able to attend. If there are members from your department you feel should be there, please let me know and I will extend an invitation to them. I thank you in advance for your support in this matter. Please let me know if you have any questions.

Sincerely,
Stephen E. Morris, MD
Director, Trauma Services
University of Utah

Please RSVP to Lisa Reynolds, trauma research nurse, at 585-0385 or lisa.reynolds@hsc.utah.edu.

Polyheme® Blood Substitute Study
Media Audit

Local Coverage

Total Media Impressions: 354,036

| <u>Date</u> | <u>Publication</u> | <u>Title</u> |
|-------------|-------------------------------------------------------------------------------------|-----------------------------------|
| 6/15 | Salt Lake Tribune Salt Lake City, UT Circ: 131,335 | Blood substitute on test in Utah |
| | Deseret Morning News Salt Lake City, UT Circ: 73,501 | Hospitals testing synthetic blood |
| | KSTU-TV (Ch. 13) Salt Lake City, UT Airtime: 5 a.m. MST Viewership: 10,400 | Synthetic Blood |
| | KUTV-TV (Ch. 2) Salt Lake City, UT Airtime: 5 a.m. MST Viewership: 14,000 | Synthetic Blood |
| 6/14 | KSL-TV (Ch. 5) Salt Lake City, UT Airtime: 6 p.m. MST Viewership: 40,800 | Synthetic Blood |
| | KUTV-TV (Ch. 2) Salt Lake City, UT Airtime: 5 p.m. MST Viewership: 39,000 | Synthetic Blood |
| | KTVX-TV (Ch. 4) Salt Lake City, UT Airtime: 5 p.m. MST Viewership: 45,000 | Synthetic Blood |

National Coverage

****Associated Press article ran in 44 publications across the country**

| <u>Date</u> | <u>Publication</u> | <u>Title</u> |
|-------------|---------------------------------|----------------------------------------------------|
| 6/17 | Casper Star Tribune (WY) | Two Salt Lake hospitals will test artificial blood |
| 6/16 | Casper Star Tribune (WY) | Two Salt Lake hospitals will test artificial blood |
| | Jackson Hole Star-Tribune (WY) | Two Salt Lake hospitals will test artificial blood |
| 6/15 | Casper Star Tribune (WY) | Two Salt Lake hospitals will test artificial blood |
| | Jackson Hole Star-Tribune (WY) | Two Salt Lake hospitals will test artificial blood |
| | Newsday (NY) | 2 Utah Hospitals to Test Artificial Blood |
| | Washington Post (D.C) | 2 Utah Hospitals to Test Artificial Blood |
| | Miami Herald (FL) | 2 Utah Hospitals to Test Artificial Blood |
| | Seattle Post Intelligencer (WA) | 2 Utah Hospitals to Test Artificial Blood |
| | Kansas City Star (MO) | 2 Utah Hospitals to Test Artificial Blood |
| | RedNova.com (TX) | 2 Utah Hospitals to Test Artificial Blood |
| | KFMB (CA) | 2 Utah Hospitals to Test Artificial Blood |
| | San Jose Mercury News (CA) | 2 Utah Hospitals to Test Artificial Blood |
| | Columbus Ledger-Enquirer (GA) | 2 Utah Hospitals to Test Artificial Blood |
| | Tallahassee.com (FL) | 2 Utah Hospitals to Test Artificial Blood |
| | Wilkes Barre Times-Leader (PA) | 2 Utah Hospitals to Test Artificial Blood |
| | Fort Wayne News Sentinel (IN) | 2 Utah Hospitals to Test Artificial Blood |
| | WTOP (D.C.) | 2 Utah Hospitals to Test Artificial Blood |

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| MLive.com (MI) | 2 Utah Hospitals to Test Artificial Blood |
| Phillyburbs.com (PA) | 2 Utah Hospitals to Test Artificial Blood |
| Grand Forks Herald (ND) | 2 Utah Hospitals to Test Artificial Blood |
| Fort Worth Star Telegram (TX) | 2 Utah Hospitals to Test Artificial Blood |
| Charlotte Observer (NC) | 2 Utah Hospitals to Test Artificial Blood |
| Myrtle Beach Sun News (SC) | 2 Utah Hospitals to Test Artificial Blood |
| Macon Telegraph (GA) | 2 Utah Hospitals to Test Artificial Blood |
| Kentucky.com (KY) | 2 Utah Hospitals to Test Artificial Blood |
| WRAL.com (NC) | 2 Utah Hospitals to Test Artificial Blood |
| Monterey County Herald (CA) | 2 Utah Hospitals to Test Artificial Blood |
| 7Online.com (NY) | 2 Utah Hospitals to Test Artificial Blood |
| Centre Daily Times (PA) | 2 Utah Hospitals to Test Artificial Blood |
| Aberdeen American News (SD) | 2 Utah Hospitals to Test Artificial Blood |
| WJLA (D.C.) | 2 Utah Hospitals to Test Artificial Blood |
| philly.com (PA) | 2 Utah Hospitals to Test Artificial Blood |
| Bradenton Herald (FL) | 2 Utah Hospitals to Test Artificial Blood |
| Kansas.com (KS) | 2 Utah Hospitals to Test Artificial Blood |
| New York Newsday (NY) | 2 Utah Hospitals to Test Artificial Blood |
| Duluth News Tribune (MN) | 2 Utah Hospitals to Test Artificial Blood |
| Worcester Telegram (MA) | 2 Utah Hospitals to Test Artificial Blood |
| Sacramento Bee (CA) | 2 Utah Hospitals to Test Artificial Blood |
| Biloxi Sun Herald (MS) | 2 Utah Hospitals to Test Artificial Blood |
| Pioneer Press (MN) | 2 Utah Hospitals to Test Artificial Blood |

The Ledger (FL)

2 Utah Hospitals to Test Artificial Blood

Wilmington Morning Star (NC)

2 Utah Hospitals to Test Artificial Blood

Tuscaloosa News (AL)

2 Utah Hospitals to Test Artificial Blood



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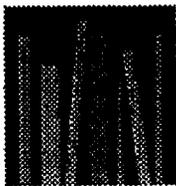


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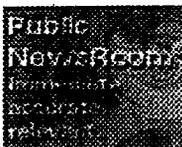


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Todd Noker (Duke Nuke'em) Reading and Signing
Wednesday, June 29, 7pm
Book Readings
King's English Bookshop, Salt Lake City

PolyHeme Blood Substitute Study
Wednesday, June 29, 6:30 pm to 8:00 pm
Community Events
West Valley Family Fitness Center, West Valley City

UMFA'S STREAMLINES: FASHIONING THE APPEARANCE OF THE MODERN WOMAN
April 1 - June 30, 10:00 am to 5:00 Tues, Thur, Fri; 11 am to 5:00 pm
Weekends; Wed, 10:00 am to 8:00 pm
Art & Museum Exhibits
Utah Museum of Fine Arts, Salt Lake City

Clean Energy Campaign
June 8 - 30, every day
Activist Groups
Utah Clean Energy, Salt Lake City

Poetry in the Park
June 23 - 30 on
Thursday 6:00 pm to 8:00 pm
Classes/Workshops
Community Writing Center, Salt Lake City

Utah's Open Records Law: Can 'GRAMA' Survive in the 21st Century?
Thursday, June 30, 6:30 pm - 8:00 pm
Lectures/Literary
Salt Lake Main Library, Salt Lake City

PolyHeme Blood Substitute Study
Thursday, June 30, 4:30 pm to 6:00 pm
Misc.
University Hospital, Salt Lake City

The Canyons' July 3rd Celebration
Sunday, July 3; 7:30pm to 10:00pm
Live Music: Funk/Reggae
The Canyons Resort, Park City

Murray Fun Days
Monday, July 4; 7:00a - 10:00p
Community Events
Murray City Park, Murray

Events Calendar

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Search by Venue
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29 2005
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Venue Listing
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University of Utah Hospital is one of a select number of trauma centers in the U.S. chosen to participate in a national clinical research study to evaluate the safety and effectiveness of PolyHeme[®], an investigational temporary oxygen-carrying red blood cell substitute, in treating critically injured and bleeding patients. Under the study protocol, treatment would begin before arrival at the hospital, either at the scene of the injury or in the ambulance and continue for 12-hours. The study will compare the survival rate of patients receiving PolyHeme to that of patients who receive the current standard of care, which is saline solution in the ambulance, followed, in the hospital, by donated blood, when needed.

The U.S. Food and Drug Administration allows for certain studies to be performed without written consent in emergency settings but only if patients have a high risk of dying without treatment, available treatments are not satisfactory, patients cannot communicate and therefore can not give consent because of their injury, and when the potential risks are reasonable. In these circumstances, patients may be given an investigational agent but only if the study has been approved in advance by an independent University group set up to review these situations.

For more information, call (801) 585-0385 or visit www.uuhsc.utah.edu/polyheme

We are seeking such approval and would like your opinion:

1. Would you be in favor of a study such as this being conducted in this community, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent?

Yes No

2. If you were severely injured and bleeding and you were being treated by the paramedics in your community, would you want to be enrolled in this type of study?

Yes No

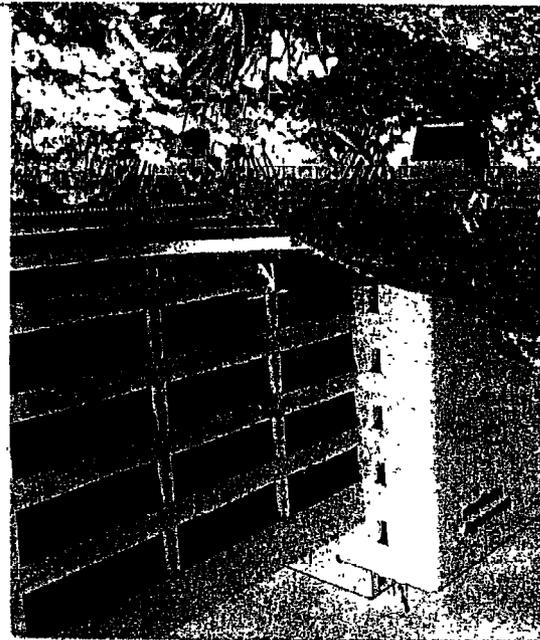
3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study?

Yes No

Do you have any comments or concerns you wish to share with us?

Zip Code _____ Age _____

Gender: Male Female



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2. If you were severely injured and bleeding and you were being treated by the paramedics in your community, would you want to be enrolled in this type of study?
 Yes No

3. If a family member of yours is severely injured and bleeding and you want to be treated by the paramedics, do you want him or her to be enrolled in this type of study?
 Yes No

Do you have any comments or questions you wish to share with us?

Zip Code _____ Age _____

Gender: Male Female



PULSE

UNIVERSITY OF UTAH HEALTH SCIENCES CENTER

June 20, 2005



Clinical Trial to Evaluate Blood Product

University and LDS hospitals have begun a period of public comment on their anticipated participation in a national clinical trial to test a new synthetic blood product in the treatment of trauma patients.

The Utah facilities are among 20 major trauma centers across the nation expected to participate in the one-year study, which will evaluate the safety and efficacy of PolyHeme®, a hemoglobin-based, oxygen-carrying blood substitute, to increase survival of critically injured and bleeding patients.

The clinical trial is being conducted under an informed consent waiver from the U.S. Food and Drug Administration (FDA) that allows for clinical research in emergency settings where it is impossible for a patient to give permission for treatment, such as in the aftermath of a motor vehicle accident.

Both the FDA and the Institutional Review Boards (IRBs) of both hospitals (responsible for initial and continuing review and approval of the study) require that broad public notification about the trial be made, giving the public an opportunity to voice any concerns.

If their IRBs approve the hospitals' participation in the trial, AirMed, Life Flight and first-responder crews from four area municipalities (Salt Lake County and Salt Lake, West Valley and Sandy cities) will begin using the blood substitute, PolyHeme®, to treat patients in hemorrhagic shock at the scene of the injury, continuing for up to 12 hours after arrival at the hospital.

A solution of chemically modified human hemoglobin that can be rapidly and massively infused, PolyHeme® has a number of advantages for use in the field, according to Stephen E. Morris, M.D., UH trauma director and principal investigator for the trial.

"It's immediately available and is compatible with all blood types," said Morris. "If we can treat trauma patients very early with an oxygen-carrying solution and keep their hemoglobin levels up, we could see more survivors."

For more information about the clinical trial and to voice an opinion on the study, visit the Web site: uhsc.utah.edu/polyheme or contact Lisa Reynolds, R.N.



UH Honored for High Donor Consent

Governor Jon Huntsman, right, recently congratulated U Hospitals & Clinics CEO Rick Fullmer, center, and Kim Phillips, R.N., M.S.N., Solid Organ Transplant manager, for the national recognition the hospital received for its exceptional organ donation consent rate.

Last month, the U.S. Department of Health and Human Services, headed by former Utah governor, Mike Leavitt, awarded Organ Donation Medals of Honor to hospitals across the nation reaching donation rates of 75 percent or higher in a 12-month period.

In 2004, UH had a 95 percent consent rate—the highest in the Intermountain West—for medically eligible donors. The national average is 50 percent and the state average is about 70 percent. LDS Hospital and Primary Children's Medical Center also were recognized with 76 percent and 100 percent rates, respectively.

Rehab Research Center Lands Funding

A new collaborative effort to more closely link rehabilitation research, education, and patient care at the U has received more than \$300,000 in funding. The University Center for Contemporary Rehabilitation Research, Education and Practice received the money in matching grants from the office of the Senior Vice President for Health Sciences, the College of Health, the School of Medicine's Division of Physical Medicine and Rehabilitation Services, and University Hospitals & Clinics.

Continued on page 2

PolyHeme® Trauma Trial

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For more information, call Lisa Reynolds, RN at (801) 585-0385 or visit www.uuhsc.utah.edu/polyheme



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PULSE

UNIVERSITY OF UTAH HEALTH SCIENCES CENTER

June 27, 2005



AAMC Reporter Notes Jung's Art

Larry Jung, M.D., professor and founder of the neonatology division in the School of Medicine's Department of Pediatrics, was featured in last month's *AAMC Reporter: News About the Nation's Medical Schools & Teaching Hospitals*.

The publication highlighted Jung's artful skill of casting bronze sculptures, something he began in 1984. "It's an escape," Jung told the reporter. "The job can be stressful, so it's quite a relief to lose myself in sculpture."

In 21 years, he has completed 15 works and has made 50 copies of each that he usually sells to friends and family while keeping a few for himself and each of his children.

Employee Lagoon Day Tickets on Sale

U Hospitals & Clinics employees may purchase discounted Lagoon tickets for the Employee Lagoon Day on July 14. Employees, with U Hospital ID, may purchase up to six discount tickets for \$20 each at Positively U, Monday-Friday, 9 a.m.-7 p.m. and Saturday, 10 a.m.-2 p.m. Tickets include a lunch or dinner coupon. Employees who cannot participate on July 14 may purchase alternate day passes for \$22.

SOM employees, with ID, can purchase alternate tickets for \$22 and a meal ticket for \$7.95 and may participate in the employee games, giveaways, and fun.

On-site staff may purchase tickets by contacting their Social Activities representative. For more information,

Noted U Neurologist Dies at Age 75

Jack H. Petajan, M.D., Ph.D., professor emeritus of neurology and School of Medicine faculty member for 36 years, died Wednesday, June 22, after a courageous battle against biliary cancer and its complications. He was 75. He remained a productive member of the Department of Neurology until shortly prior to his death.



Jack H. Petajan

Born in Evanston, Ill., Petajan graduated in biology from Johns Hopkins University and received his medical degree and doctorate in physiology from the University of Wisconsin Medical School. He served fellowships at the Mayo Clinic in Rochester, Minn., and the Brain Research Institute at the University of Zurich, Switzerland. From 1965-69 he worked for the U.S. Public Health Service in Alaska, also serving as a visiting professor of physiology at the University of Alaska.

Petajan came to the University of Utah in 1969 and became professor of neurology in 1973. He was a highly productive and valued clinician, investigator, and teacher throughout his long career. Petajan developed the Clinical Neurophysiology Laboratory and established the University's Multiple Sclerosis clinic, which he supervised for many years.

Regarded as a world-class clinician, diagnostician, and researcher, Petajan received more than 20 research grants to study multiple sclerosis, Parkinson's disease, and neuromuscular diseases. He served as president of the American Academy of Electrodiagnostic Medicine and was on the board of directors of many organizations, including the Myasthenia Gravis Foundation, the National Multiple Sclerosis Society, and the National Amyotrophic Lateral Foundation. He published extensively in neuromuscular disease, multiple sclerosis, and a variety of other neurophysiology. His many honors included selection as a Fellow of the American Academy

Petajan continued

"Jack was nationally and internationally known for the quality and originality of his work," John E. Greenlee, M.D., professor and interim chair of neurology, said of his longtime colleague. "He possessed enormous curiosity—about medicine and all of life and had a wonderful sense of humor. But more than that, he was an absolutely unselfish and decent man. He brought extraordinary compassion to the care of his patients. In his own clinical practice and in all of his teaching, he emphasized the importance of each patient as an individual human being."

In 2003, the Department of Neurology held a symposium in honor of Petajan and also named its new Electromyography Laboratory for him. The neurology residents also honored Dr. Petajan for his extraordinary teaching ability with a lifetime teaching award.

Petajan possessed a lifelong love of music. He performed with string groups and also sang with the Utah Symphony Choir and Pro Musica Chamber Choir.

He is survived by his wife Mary Eve Sanford, Ph.D., who serves as adjunct faculty with the Department of Psychiatry; his children Eric (Cori), Anne (Dan) Chisholm, Amy (Glenn) McMinn, Bo David, five grandchildren, numerous nieces and nephews; and his sole surviving brother, Albert (Sylvia) Petajan, of Kewaunee, Wis.

Donations may be made to the National Jack Petajan Memorial Fund, National MS Society, Utah State Chapter, 2995 S. West Temple, Suite C., Salt Lake City, Utah, 84115.

MICU Relocated During Renovation

Beginning this Tuesday, patients in the hospital's Medical Intensive Care Unit (MICU) will be temporarily relocated to the second floor of the Eccles Critical Care Pavilion while the MICU is renovated. The nursing unit/bed/room in the Allegra and Olympus systems will not be altered.

For a crosswalk table of temporary room numbers and list of contact numbers, please refer to the Clinical Resources page accessible via the "Daily Dose" intranet at <http://intranet.uuhsc.utah.edu>.

* PolyHeme Public Meeting Scheduled

A community meeting regarding the hospital's participation in the clinical trial of new synthetic blood product is scheduled for this Thursday from 4:30-6 p.m. in Classroom B. For information, contact Lisa Reynolds, RN, at 325-0225.



RNs Complete Residency Training

Some 23 UH nurses recently completed the year-long Nurse Residency Program developed by the University Health System Consortium and the American Association of Colleges of Nursing. The program, which includes all new nurse graduates, focuses on developing decision-making skills, critical thinking, research-based practice, communication, leadership, and patient safety, according to residency program coordinators Roxanne Bowers, R.N., and Connie Madden, R.N.

Pictured, left to right, are nurse graduates Kelly Noakes, Erin Davis, Emily Southers, Ericka Drown, Saralynn Mallory, Wayne Kinsey, Amy Silliman, Kitt Slaid, Jennifer Kovich, Jennie Bingham, Mandy Nicholls, Angelique Khan, Mindi Davidson, and Lauren Olsen. Kneeling are Chad Bagley and John Stark. Not pictured are Mindy Stubbs, Stephanie Keeler, Aaron Page, Sarah Lauer, Alison Bishop, Michael Vance, and John Mitchell.

UUSAC Seeks Staff for U Panel

The University of Utah Staff Advisory Council (UUSAC) is seeking candidates to serve on the University's Employment and Discrimination Complaints Hearing Panel. The committee, comprised of 45 staff members, hears appeals related to adverse employment actions, including reductions in force, written warnings, suspensions without pay, demotions, and involuntary terminations.

They also participate in discrimination and sexual harassment appeal hearings. Employees interested in serving on the UUSAC committee should complete the form located online at www.utah.edu/uusac. For more information, contact Mary Ann Call, x1-8365 or e-mail her at marv.ann.call@hsc.utah.edu.

PolyHeme® Trauma Trial

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(2150 East 4800 South)**
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For more information, call Lisa Reynolds, RN at (801) 585-0385 or visit www.uuhsc.utah.edu/polyheme



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2 Sections of Bull Paper 5-1

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For more information, call Lisa Reynolds, RN at (801) 585-0385 or visit www.uuhsc.utah.edu/polyheme



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Dedicated to the Community. Part of your life.*

COMMUNITY MEETING FOR THE POLYHEME TRAUMA TRIAL

Sandy Library, 10100 South 1300 East
June 21, 2005, 4:30 to 6:00 pm

AGENDA

**POLYHEME® TRAUMA TRIAL
COMMUNITY MEETING AT THE SANDY LIBRARY**

A Phase III, Randomized, Controlled, Open-Label Multicenter, 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

| | | |
|---------|---------------------------------|------------------------------------|
| 4:30 pm | Welcome and Introductions | Lisa Reynolds, RN |
| 4:35 pm | Federal regulations and the IRB | Anna Shirley, IRB Administrator |
| 4:45 pm | Explanation of PolyHeme® trial | Stephen E. Morris, MD |
| 5:15 pm | Questions and Answers | Stephen E. Morris, MD |
| 6:00 pm | Adjourn | |

Handouts are available at the back of the room.

POLYHEME® TRAUMA TRIAL
Community Consultation Feedback Form
for University of Utah Hospital, held at the
Sandy Library
June 21, 2005
from 4:30 pm to 6:00 pm

Please circle your answers

1. Would you support a study such as the one described at this meeting being conducted in this community, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent?

Yes No

2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study?

Yes No

3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study?

Yes No

4. Do you have any comments or concerns you wish to share with us?

Age: _____

Gender: Male _____ Female _____

Thank you for your participation today.
Please call Lisa Reynolds, RN at 801-585-0385 or visit the
website: uuhsc.utah.edu/polyheme for more information.

COMMUNITY MEETING FOR THE POLYHEME TRAUMA TRIAL

Holladay Library
2150 East 4800 South
June 27, 2005, 6:30 to 8:00 pm

AGENDA

POLYHEME® TRAUMA TRIAL COMMUNITY MEETING at the Holladay Library

A Phase III, Randomized, Controlled, Open-Label Multicenter, 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

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Community Consultation Feedback Form
for University of Utah Hospital, held at the
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COMMUNITY MEETING FOR THE POLYHEME TRAUMA TRIAL

West Valley Family Center
5415 West 3100 South
June 29, 2005, 6:30 to 8:00 pm

AGENDA

POLYHEME® TRAUMA TRIAL COMMUNITY MEETING in West Valley City

A Phase III, Randomized, Controlled, Open-Label Multicenter, 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

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POLYHEME® TRAUMA TRIAL
Community Consultation Feedback Form
for University of Utah Hospital, held at the
West Valley Fitness Center
Classrooms B and C
from 6:30 pm to 8:00 pm

Please circle your answers

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Yes No

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COMMUNITY MEETING FOR THE POLYHEME TRAUMA TRIAL

University of Utah Hospital
Classroom B
June 30, 2005, 4:30 to 6:00 pm

AGENDA

POLYHEME® TRAUMA TRIAL COMMUNITY MEETING AT University Hospital

A Phase III, Randomized, Controlled, Open-Label Multicenter, 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

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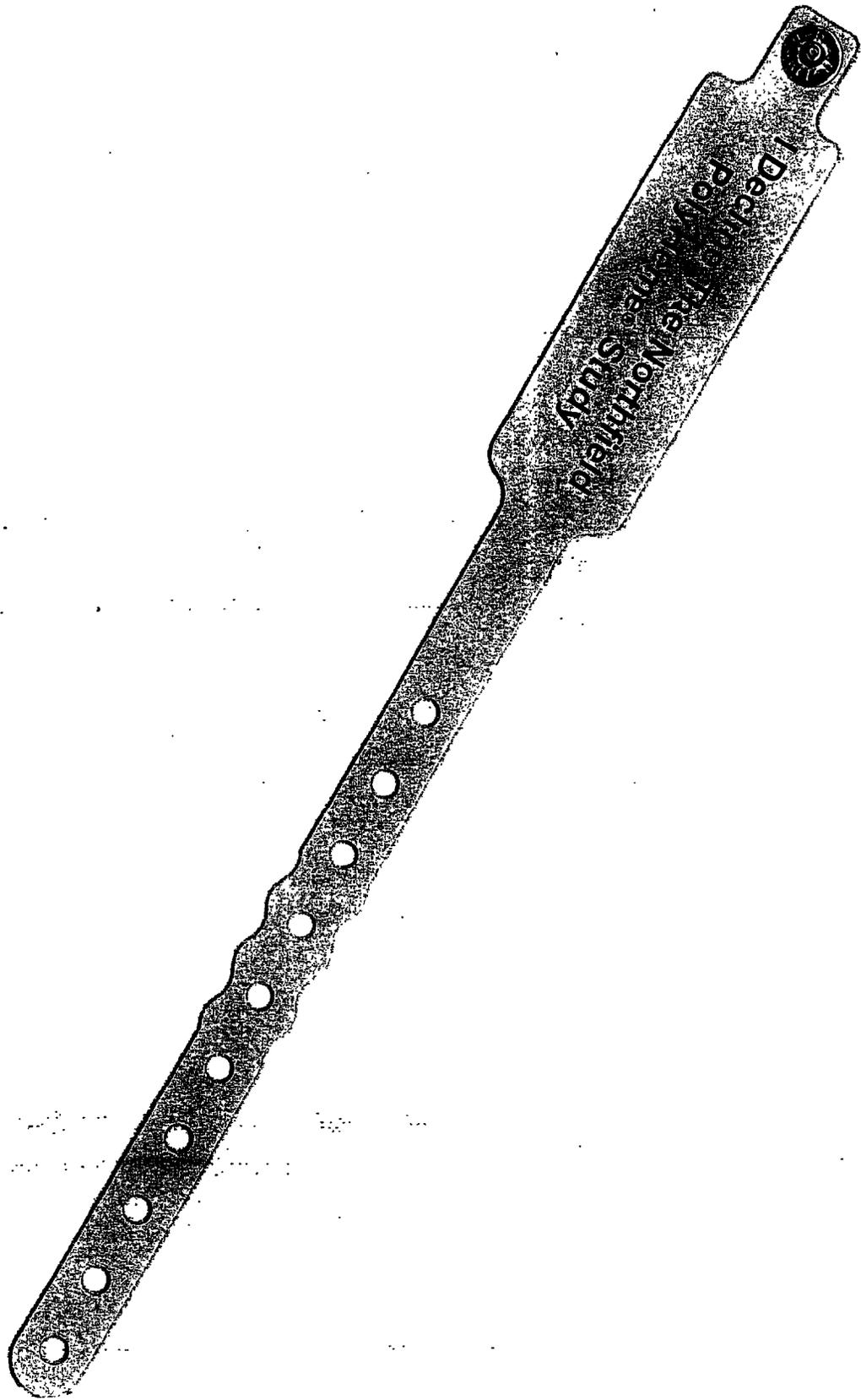
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PolyHeme® Trauma Trial

Community Consultation

University Hospital
LDS Hospital
Salt Lake City, UT
21 June 2005

website: <http://uohsc.utah.edu/surgery/divisions/general/polyheme/>

Clinical Investigators

- Stephen E. Morris, MD, FACS
Trauma Director, University Hospital
telephone: 801-581-6255
- Harrison Lazarus, MD, FACS
Trauma Surgeon, LDS Hospital
telephone: 801-263-0778

Study Sponsor

Northfield Laboratories Inc.

- Developer of the oxygen-carrying resuscitative fluid called PolyHeme®
- Conducted multiple studies with PolyHeme over the past decade
- Most studies have been with injured trauma patients
- Company website: www.northfieldlabs.com

Study Purpose

To evaluate the life-sustaining potential of PolyHeme® when given to severely injured and bleeding patients in “hemorrhagic shock,” starting at the scene of injury

What is Hemorrhagic Shock?

Hemorrhagic: massive loss of blood

Shock: life-threatening condition

- Dangerously low blood pressure
- Internal organs don't receive enough oxygen and have difficulty functioning
- Might lead to death

Need for Improved Outcome

- The Center for Disease Control (CDC) lists trauma as the leading cause of death among Americans under age 45
- Thousands of trauma patients die each year
- Many of these patients die because the “standard of care” cannot reverse the damaging effects of hemorrhagic shock

What is the Standard of Care?

Represents the current treatment

In the Ambulance

The patient receives
salt water
(blood is not available)

In the Hospital

The patient receives
salt water
and donated blood

Standard of Care Limitations

In the Ambulance

- Salt water does not carry oxygen, unlike blood
- Without enough oxygen, the body and its internal organs have difficulty functioning and can stop working (organ failure)

Standard of Care Limitations

In the Hospital

- Risks associated with large infusions of donated blood in trauma patients have been identified
- Increase in immune function, which may cause failure of vital organs and death, observed in some patients who have received transfusions¹

¹A. Sauaia et al., *Archives of Surgery* (1994),
Volume 129:39-45

What is PolyHeme®?

*A temporary red
blood cell
substitute
that carries oxygen*

*In the acute setting, 1
unit (pint) of
PolyHeme is given in
place of 1 unit (pint)
of blood*



What is PolyHeme®?

- Made from human blood
- Compatible with all blood types
- Immediately available
- Manufactured with steps to reduce the risk of viral transmission



Why Use PolyHeme®?

- PolyHeme was developed to treat urgent, large volume blood loss
 - Blood is not normally available in the ambulance
 - PolyHeme will be immediately available in the ambulance and carries oxygen
- PolyHeme may reduce the use of donated blood in the first 12 hours after injury, and might avoid potential organ failure

Why Use PolyHeme®?

- There are risks associated with large infusions of donated blood in trauma patients¹
- In a controlled Phase II trial in hospitalized trauma patients, higher levels of immune markers were seen in patients who received blood transfusions as compared to those who received PolyHeme²

¹A. Sauaia et al., *Archives of Surgery* (1994), Volume 129:39-45

²E. E. Moore, *Journal of American College of Surgeons* (2003), Volume 196 (1)

Why Use PolyHeme®?

To evaluate a potential improvement in survival of severely injured and bleeding patients

PolyHeme® Experience: Past

- Administered to patients with acute blood loss in the hospital setting
- Patients have received up to 20 units (pints) or 1,000 gm of PolyHeme®
 - Normal volume of blood in a human is 10 units (pints) or 500 gm of hemoglobin
- Some of these patients kept alive while losing virtually all of their own blood during ongoing bleeding and receiving only PolyHeme® as replacement.

PolyHeme® Experience: Past

- Observations in these patients have suggested the life-sustaining potential of PolyHeme® in the treatment of urgent life-threatening blood loss and life-threatening hemoglobin levels

[Gould et al, Journal of American College of Surgeons (2002), Volume 195 (4)]

PolyHeme® Experience: Past

- During the course of evaluation of any investigational product, both adverse experiences and serious adverse experiences can occur. These may be due to either:
 - the underlying condition of the patient
 - the treatment setting or
 - the investigational product itself
- Both adverse experiences and serious adverse experiences have occurred in prior studies.

PolyHeme® Experience: Past

- One trial conducted in older patients undergoing elective surgery for abdominal aortic aneurysm that involved a non-routine procedure where up to 60% of their own blood was removed and later replaced.
 - Serious adverse events, including cardiovascular, were observed.
 - It cannot be determined whether due to experimental procedure or PolyHeme itself.
- Patients in this study were older with more cardiovascular risk factors than those in the trials in trauma patients.

PolyHeme® Experience: Past

- In trauma patients, PolyHeme® has been rapidly infused during urgent life-threatening blood loss in sufficiently large quantities, up to 20 units (pints), to be considered well-tolerated in this patient population.

[Gould et al, Journal of American College of Surgeons (2002), Volume 195 (4)]

PolyHeme® Experience: Current Trial

- 720 patients will be enrolled:
 - 360 patients in the control group
 - 360 patients in the PolyHeme® group
- Currently, enrollment underway at a 17 Level I trauma centers across the United States
 - A list of centers is available at www.clinicaltrials.gov
- The FDA has approved the study
- 22 Institutional Review Boards have approved the study. 1 IRB has not approved the study

PolyHeme® Experience: Current Trial

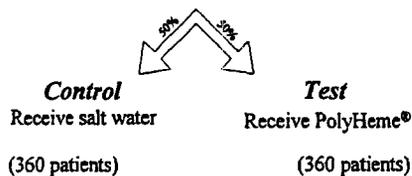
- An Independent Data Monitoring Committee set up to review mortality and serious adverse experiences after 60, 120, 250 and 500 patients have been enrolled and followed for 30 days
- Committee has reviewed the safety data on the first 60, 120 and 250 patients
- Committee has recommended that the study continue without any change

PolyHeme® Experience: Current Trial

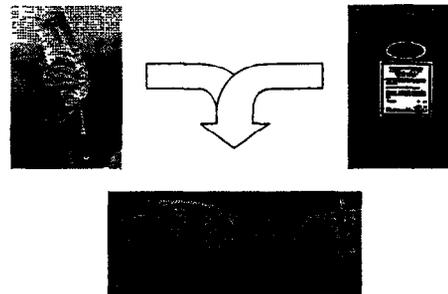
- At the 250 patient look, Committee conducted an adaptive sample size determination.
- Assessment was based on a comparison between the mortality rate predicted in the protocol and the observed mortality rate in the trial to date.
- Committee has concluded that no adjustment in the number of patients to be enrolled in the study is required.

Trial Design: Before the Hospital

Severely injured trauma patients will be assigned to either one of two groups by chance



Ambulance Infusion



Trial Design: At the Hospital

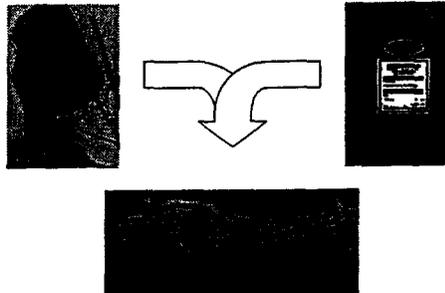
Control

- Salt water for hydration
- Donated blood to boost oxygen levels

Test

- Salt water for hydration
- PolyHeme® to boost oxygen levels
- Maximum dose of 6 units during first 12 hours
- Donated blood will be used thereafter

Hospital Infusion



Who Would Be Included?

Patients at risk of dying

- Who have sustained severe injuries
- Who have lost a large amount of blood and are in shock
- Who are at least 18 years old
- Who are of either gender (male or female)

Who Would Be Excluded?

- Patients who are obviously pregnant
- Patients who have severe head or brain injuries
- Patients who have "unsurvivable" injuries
- Patients who require CPR
- Patients with known objections to blood transfusions
- Patients with known orders not to resuscitate
- Patient with visible or identifiable method of objection (e.g. wearing exclusion bracelet)

FDA Review

- Northfield Laboratories received clearance to proceed with this study from the Food and Drug Administration (FDA)
- The FDA authorized the use of an exception from informed consent requirements for this study

What is Informed Consent?

A process by which patients make informed decisions about participating in research studies

- Traditionally required for all research studies
- Research studies compare 2 treatments (standard vs. investigational)
- Doctors describe each of these potential treatments

What is Informed Consent?

A process by which patients make informed decisions about participating in research studies

- Patients are informed of the potential risks and potential benefits associated with each of these treatments
- Patients choose whether to participate in the study

What is Exception from Informed Consent?

Patients are enrolled in a research study without giving their informed consent

How Can That Be?

A federal regulation (21 CFR 50.24), created in 1996, allows certain studies that meet the following criteria to use this exception

- Patients' lives must be at risk
- Available treatments are not satisfactory
- Patients are unable to give consent
- Potential risks are reasonable

How Can That Be?

A federal regulation (21 CFR 50.24), created in 1996, allows certain studies that meet the following criteria to use this exception

- Participation in the research could provide a direct benefit (increased survival) to the patient
- The research could not be practicably carried out without an exemption

Consent Safeguards

- If possible, the patient or a legally authorized representative (LAR) can give consent before the patient is enrolled in the study

Consent Safeguards

- If consent cannot be obtained before enrollment, frequent attempts will be made to contact the patient's LAR and family to describe the study
- The patient, family members, or a legally authorized representative may decide to withdraw the patient at any time

Potential Benefits of PolyHeme®

- Can enhance the amount of vital oxygen in the patient's blood (prehospital setting)
- May avoid failure of vital organs (prehospital and hospital settings)
- Might increase the likelihood of survival
- Is compatible with all blood types
- Is immediately available
- Manufactured with steps to reduce the risk of viral transmission

Potential Risks of PolyHeme®

- Rash
- Increased blood pressure
- Kidney or liver damage
- Viral infection (HIV, hepatitis, etc.)
- Unforeseen happenings

Patient Protection

The Institutional Review Board (IRB) is a group of medical, scientific, and nonscientific members of the community

- Reviews all proposals for research on humans
- Assures patient safety
- Monitors community feedback

Patient Protection

- The IRB will decide whether or not to allow this hospital to participate in the PolyHeme® trial
- An Independent Data Monitoring Committee is overseeing the trial to monitor the safety of the product
- The FDA is being informed of the trial's progress

If We Participate...

- The results of the study will be revealed to the community after the trial has been completed
- Those who do not want to participate in the study can wear a special bracelet to exclude themselves

Questions
or
Comments?

**UNIVERSITY OF UTAH
"BLOOD SUBSTITUTE" STUDY**

PUBLIC RESPONSE IS INVITED

AN INFORMATIONAL DISCUSSION WILL BE HELD

JUNE 30, 2005

**UNIVERSITY OF UTAH HOSPITAL
CLASSROOM "B"
(2ND FLOOR OFF B ELEVATORS)**

4:30 – 6:00 P.M.

**TRAUMA SERVICES FROM THE UNIVERSITY OF UTAH
WILL HOLD A DISCUSSION ON THE BLOOD SUBSTITUTE POLYHEME[®]**

**DR. STEPHEN MORRIS WILL EXPLAIN THE PURPOSE AND
ADDRESS ANY PUBLIC CONCERNS.**

PLEASE PLAN TO ATTEND!

Bracelet Log
(declining the study)

| | | |
|----------|------------------------------------------------------------|--|
| 6-14-05 | | |
| 2 | (given to Media) | |
| 6-15-02 | | |
| 6 | (given to a family, in person) | |
| 1 | (mailed at request from website) | |
| 6-16-05 | | |
| 3 | (mailed to a family at request from website) | |
| 6-21-05 | | |
| 6 | (given to a family at the first community meeting) | |
| 6-27-05 | | |
| 7 | (mailed to a family at request from website) | |
| 6-28-05 | | |
| 1 | (mailed at request from website) | |
| 6-29-05 | | |
| 1 | (mailed at request from website) | |
| 8-01-05 | | |
| 4 | (mailed at request from website) | |
| 10-11-05 | | |
| 220 | (at request of IRB, to 12 local opposing religious groups) | |

Total 251 as of 10-11-05

Bracelet Log
(declining the study)

| | | |
|---------|---|----------------------------------------------|
| 6-14-05 | 2 | (to Media) |
| 6-15-05 | 6 | (to a family in person) |
| | 1 | (mailed at request from website) |
| 6-16-05 | 3 | (to a family at request from website) |
| 6-21-05 | 6 | (to a family at the first community meeting) |
| 6-27-05 | 7 | (to a family at request from website) |
| 6-28-05 | 1 | (at request from website) |
| 6-29-05 | 1 | (at request from website) |
| 8-01-05 | 4 | (at request from website) |

TOTAL 31 as of 8-1-05

Bracelet Log
(declining the study)

| | | |
|---------|---|----------------------------------------------|
| 6-14-05 | 2 | (to Media) |
| 6-15-05 | 6 | (to a family in person) |
| | 1 | (mailed at request from website) |
| 6-16-05 | 3 | (to a family at request from website) |
| 6-21-05 | 6 | (to a family at the first community meeting) |
| 6-27-05 | 7 | (to a family at request from website) |
| 6-28-05 | 1 | (at request from website) |
| 6-29-05 | 1 | (at request from website) |

TOTAL 27 as of 7-6-05

Community Feedback
PolyHeme Study

Feedback Forms: As of 9-26-05

1. Internet (from the Website) 23 total, 18 yes, 5 no
2. Community meeting forms: 6 total, 6 yes, 0 no
3. Post Cards (business reply) 137 total, 107 yes, 30 no

Total: 166 as 9-26-05

(131 yes 35 no)

Community Feedback **PolyHeme Study**

Feedback Forms: As of 8-25-05

1. Internet (from the Website) 22 total, 17 yes, 5 no
2. Community meeting forms: 6 total, 6 yes, 0 no
3. Post Cards (business reply) 137 total, 107 yes, 30 no

Total: 165 as 8-25-05

(130 yes 35 no)

Community Feedback PolyHeme Study

Feedback Forms: As of 8-17-05

1. Internet (from the Website) 21 total, 16 yes, 5 no
2. Community meeting forms: 6 total, 6 yes, 0 no
3. Post Cards (business reply) 137 total, 107 yes, 30 no

Total: 164 as 8-17-05

(129 yes 35 no)

Community Feedback PolyHeme Study

Feedback Forms: As of 8-15-05

1. Internet (from the Website) 21 total, 16 yes, 5 no
2. Community meeting forms: 6 total, 6 yes, 0 no
3. Post Cards (business reply) 136 total, 106 yes, 30 no

Total: 163 as 8-15-05

(128 yes 35 no)

Community Feedback **PolyHeme Study**

Feedback Forms: As of 8-8-05

1. Internet (Website) 20 total, 15 yes, 5 no
2. Community meeting forms: 6 total, 6 yes, 0 no
3. Post Cards (business reply) 136 total, 106 yes, 30 no

Total: 162 as 8-8-05

(127 yes 35 no)

Community Feedback **PolyHeme Study**

Feedback Forms: As of 8-1-05

1. Internet (Website) 20 total, 15 yes, 5 no
2. Community meeting forms: 6 total, 6 yes, 0 no
3. Post Cards (business reply) 134 total, 104 yes, 30 no

Total: 160 as 8-1-05

(126 yes 34 no)

Community Feedback PolyHeme Study

Feedback Forms: As of 7-20-05

1. Internet (Website) 17 total, 14 yes, 3 no
2. Community meeting forms: 6 total, 6 yes, 0 no
3. Post Cards (business reply) 131 total, 101 yes, 30 no

Total: 154 as 7-20-05

(121 yes 33 no)

Community Feedback **PolyHeme Study**

Feedback Forms: As of 7-19-05

1. Internet (Website) 16 total, 13 yes, 3 no
2. Community meeting forms: 6 total, 6 yes, 0 no
3. Post Cards (business reply) 131 total, 101 yes, 30 no

Total: 153 as 7-19-05

(120 yes 33 no)

Community Feedback **PolyHeme Study**

Feedback Forms: As of 7-8-05

1. Internet (Website) 15 total, 12 yes, 3 no
2. Community meeting forms: 6 total, 6 yes, 0 no
3. Post Cards (business reply) 117 total, 90 yes, 27 no

Total: 138 as 7-8-05

(108 yes 30 no)

Community Feedback PolyHeme Study

Feedback Forms: As of 7-6-05

1. Internet (Website) 14 total, 11 yes, 3 no
2. Community meeting forms: 6 total, 6 yes, 0 no
3. Post Cards (business reply) 79 total, 58 yes, 21 no

Total: 99 as of 7-6-05



June 29th, 2005

Kingdom Hall
Jehovah's Witness, Holladay Congregation
2595 East Wren Road
Salt Lake City, Utah 84117

Dear Kingdom Hall,

University Hospital has been chosen to be one of few level one trauma centers to conduct a research study using PolyHeme[®], a blood substitute, to treat severely injured and bleeding patients. We feel it is important to inform you and other Kingdom Halls in the area of this research study because patients in this study will be randomized at the scene of injury to receive either PolyHeme (investigational treatment) or the standard of care (salt water and donated blood) without obtaining their informed consent to participate in the study. We take into strong consideration your beliefs and feel as though you should be informed about the study and how it works.

Most importantly, we want you to know that one of the exclusion criteria for the study is "a known objection to blood." Therefore, this study will not enroll Jehovah's Witnesses, provided that the paramedics can identify you as such, because the investigators recognize that you cannot be randomly assigned to receive blood upon arrival to the hospital. In addition, we recognize that choosing to accept PolyHeme would be a matter of personal conscience since it is made from human hemoglobin, and in the event that you suffer a traumatic injury, you would most likely be physically and emotionally unable to make this decision. It is important that you identify yourself as a Jehovah's Witness (card, bracelet, etc.) so that, if you are injured, you are not accidentally enrolled into this study.

The purpose of this study is to examine the safety and effectiveness of PolyHeme as a red blood cell substitute in (a) the prehospital setting where blood is not available and (b) the 12-hour period after injury during which blood will be used as the comparator. In the Salt Lake City area proper, PolyHeme will be carried on ambulances and will begin to be infused in the prehospital setting to those patients randomized to the investigational group by the paramedics under strict guidelines and regulations given by the Food and Drug Administration (FDA). The research trial will be supervised by University Hospital Institutional Review Board and reported to the FDA.

School of Medicine
Department of Surgery
Stephen E. Morris, M.D., F.A.C.S.
Associate Professor
30 North 1900 East
Salt Lake City, Utah 84132
(801) 581-6255
FAX (801) 587-9149

Page 2

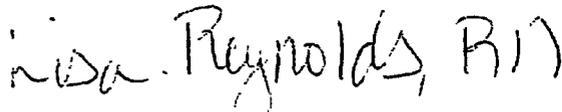
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If you would like to learn more about this study, or if you have any questions or concerns, please feel free to contact me or my study coordinator at anytime.

Sincerely,



Stephen E. Morris, MD
Director of Trauma Services
University of Utah Medical Center
30 North 1900 East, 3B110
Salt Lake City, Utah 84132
801-581-6255



Lisa Reynolds, RN
Clinical Research Coordinator
University of Utah Medical Center
30 North 1900 East, 3B301
Salt Lake City, Utah 84132
801-585-0385



June 29th, 2005

Kingdom Hall
Jehovah's Witness, Bountiful Congregation
355 E 900 N
Bountiful, Utah 84010

Dear Kingdom Hall,

University Hospital has been chosen to be one of few level one trauma centers to conduct a research study using PolyHeme[®], a blood substitute, to treat severely injured and bleeding patients. We feel it is important to inform you and other Kingdom Halls in the area of this research study because patients in this study will be randomized at the scene of injury to receive either PolyHeme (investigational treatment) or the standard of care (salt water and donated blood) without obtaining their informed consent to participate in the study. We take into strong consideration your beliefs and feel as though you should be informed about the study and how it works.

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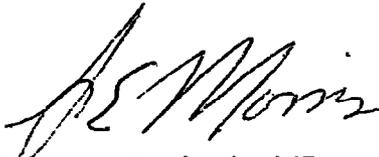
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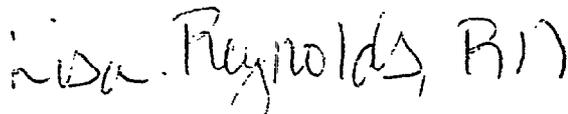
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If you would like to learn more about this study, or if you have any questions or concerns, please feel free to contact me or my study coordinator at anytime.

Sincerely,



Stephen E. Morris, MD
Director of Trauma Services
University of Utah Medical Center
30 North 1900 East, 3B110
Salt Lake City, Utah 84132
801-581-6255



Lisa Reynolds, RN
Clinical Research Coordinator
University of Utah Medical Center
30 North 1900 East, 3B301
Salt Lake City, Utah 84132
801-585-0385



June 29th, 2005

Kingdom Hall
Jehovah's Witness, West Jordan Congregation
6148 S 4590 W
Salt Lake City, Utah 84118

Dear Kingdom Hall,

University Hospital has been chosen to be one of few level one trauma centers to conduct a research study using PolyHeme[®], a blood substitute, to treat severely injured and bleeding patients. We feel it is important to inform you and other Kingdom Halls in the area of this research study because patients in this study will be randomized at the scene of injury to receive either PolyHeme (investigational treatment) or the standard of care (salt water and donated blood) without obtaining their informed consent to participate in the study. We take into strong consideration your beliefs and feel as though you should be informed about the study and how it works.

Most importantly, we want you to know that one of the exclusion criteria for the study is "a known objection to blood." Therefore, this study will not enroll Jehovah's Witnesses, provided that the paramedics can identify you as such, because the investigators recognize that you cannot be randomly assigned to receive blood upon arrival to the hospital. In addition, we recognize that choosing to accept PolyHeme would be a matter of personal conscience since it is made from human hemoglobin, and in the event that you suffer a traumatic injury, you would most likely be physically and emotionally unable to make this decision. It is important that you identify yourself as a Jehovah's Witness (card, bracelet, etc.) so that, if you are injured, you are not accidentally enrolled into this study.

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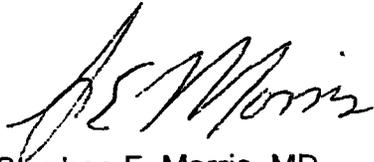
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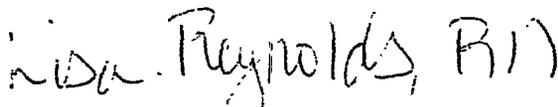
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If you would like to learn more about this study, or if you have any questions or concerns, please feel free to contact me or my study coordinator at anytime.

Sincerely,



Stephen E. Morris, MD
Director of Trauma Services
University of Utah Medical Center
30 North 1900 East, 3B110
Salt Lake City, Utah 84132
801-581-6255



Lisa Reynolds, RN
Clinical Research Coordinator
University of Utah Medical Center
30 North 1900 East, 3B301
Salt Lake City, Utah 84132
801-585-0385



June 29th, 2005

Kingdom Hall
Jehovah's Witness, Sandy Congregation
8836 S 300 E
Sandy, Utah 84070

Dear Kingdom Hall,

University Hospital has been chosen to be one of few level one trauma centers to conduct a research study using PolyHeme[®], a blood substitute, to treat severely injured and bleeding patients. We feel it is important to inform you and other Kingdom Halls in the area of this research study because patients in this study will be randomized at the scene of injury to receive either PolyHeme (investigational treatment) or the standard of care (salt water and donated blood) without obtaining their informed consent to participate in the study. We take into strong consideration your beliefs and feel as though you should be informed about the study and how it works.

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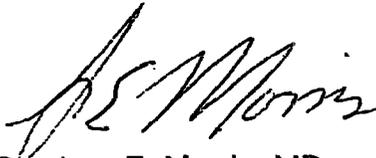
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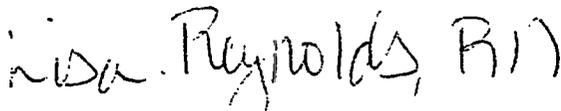
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Lisa Reynolds, RN
Clinical Research Coordinator
University of Utah Medical Center
30 North 1900 East, 3B301
Salt Lake City, Utah 84132
801-585-0385



June 29th, 2005

Kingdom Hall
Jehovah's Witness, Magna Congregation
3164 S 7200 W
Magna, Utah 84044

Dear Kingdom Hall,

University Hospital has been chosen to be one of few level one trauma centers to conduct a research study using PolyHeme[®], a blood substitute, to treat severely injured and bleeding patients. We feel it is important to inform you and other Kingdom Halls in the area of this research study because patients in this study will be randomized at the scene of injury to receive either PolyHeme (investigational treatment) or the standard of care (salt water and donated blood) without obtaining their informed consent to participate in the study. We take into strong consideration your beliefs and feel as though you should be informed about the study and how it works.

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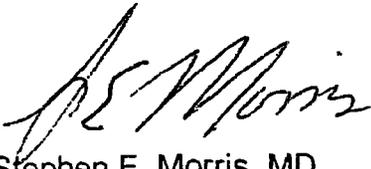
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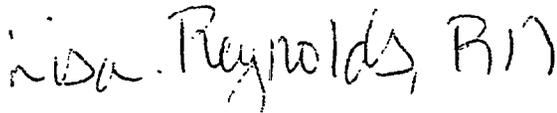
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If you would like to learn more about this study, or if you have any questions or concerns, please feel free to contact me or my study coordinator at anytime.

Sincerely,



Stephen E. Morris, MD
Director of Trauma Services
University of Utah Medical Center
30 North 1900 East, 3B110
Salt Lake City, Utah 84132
801-581-6255



Lisa Reynolds, RN
Clinical Research Coordinator
University of Utah Medical Center
30 North 1900 East, 3B301
Salt Lake City, Utah 84132
801-585-0385



June 29th, 2005

West Jordan Seventh Day Adventist Church
2125 W 9000 South
West Jordan, Utah 84088

Dear Congregation,

University Hospital has been chosen to be one of few level one trauma centers to conduct a research study using PolyHeme[®], a blood substitute, to treat severely injured and bleeding patients. We feel it is important to inform those in the area of this research study because patients in this study will be randomized at the scene of injury to receive either PolyHeme (investigational treatment) or the standard of care (salt water and donated blood) without obtaining their informed consent to participate in the study. We take into strong consideration your beliefs and feel as though you should be informed about the study and how it works.

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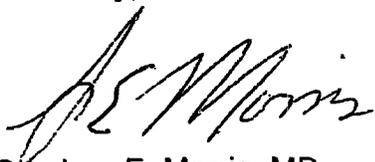
School of Medicine
Department of Surgery
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(801) 581-6255
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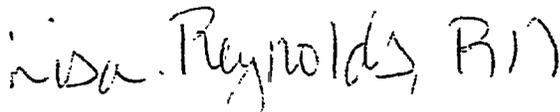
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801-581-6255



Lisa Reynolds, RN
Clinical Research Coordinator
University of Utah Medical Center
30 North 1900 East, 3B301
Salt Lake City, Utah 84132
801-585-0385



June 29th, 2005

Seventh Day Adventist Church
2139 S Foothill Drive
Salt Lake City, Utah 84108

Dear Congregation,

University Hospital has been chosen to be one of few level one trauma centers to conduct a research study using PolyHeme[®], a blood substitute, to treat severely injured and bleeding patients. We feel it is important to inform those in the area of this research study because patients in this study will be randomized at the scene of injury to receive either PolyHeme (investigational treatment) or the standard of care (salt water and donated blood) without obtaining their informed consent to participate in the study. We take into strong consideration your beliefs and feel as though you should be informed about the study and how it works.

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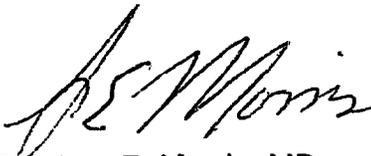
School of Medicine
Department of Surgery
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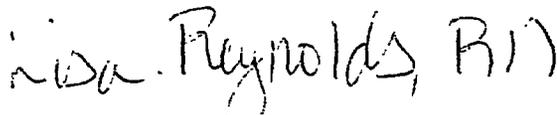
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Salt Lake City, Utah 84132
801-581-6255



Lisa Reynolds, RN
Clinical Research Coordinator
University of Utah Medical Center
30 North 1900 East, 3B301
Salt Lake City, Utah 84132
801-585-0385



June 29th, 2005

Central Seventh Day Adventist Church
460 S 800 East
Salt Lake City, Utah 84102

Dear Congregation,

University Hospital has been chosen to be one of few level one trauma centers to conduct a research study using PolyHeme[®], a blood substitute, to treat severely injured and bleeding patients. We feel it is important to inform those in the area of this research study because patients in this study will be randomized at the scene of injury to receive either PolyHeme (investigational treatment) or the standard of care (salt water and donated blood) without obtaining their informed consent to participate in the study. We take into strong consideration your beliefs and feel as though you should be informed about the study and how it works.

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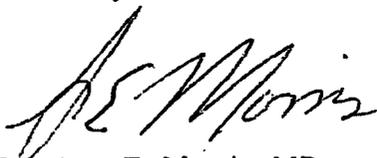
School of Medicine
Department of Surgery
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Associate Professor
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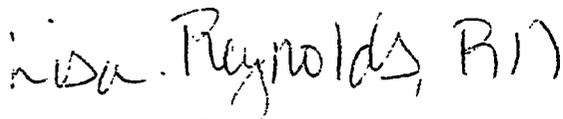
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Lisa Reynolds, RN
Clinical Research Coordinator
University of Utah Medical Center
30 North 1900 East, 3B301
Salt Lake City, Utah 84132
801-585-0385



June 29th, 2005

Church of Christian Science
Third Church
1306 E Spring Lane
Salt Lake City, Utah 84117

Dear Congregation,

University Hospital has been chosen to be one of few level one trauma centers to conduct a research study using PolyHeme[®], a blood substitute, to treat severely injured and bleeding patients. We feel it is important to inform those in the area of this research study because patients in this study will be randomized at the scene of injury to receive either PolyHeme (investigational treatment) or the standard of care (salt water and donated blood) without obtaining their informed consent to participate in the study. We take into strong consideration your beliefs and feel as though you should be informed about the study and how it works.

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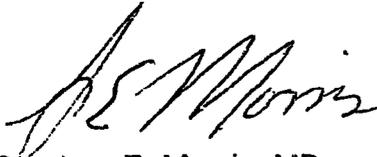
School of Medicine
Department of Surgery
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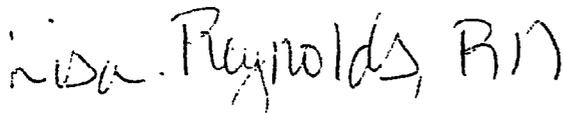
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Salt Lake City, Utah 84132
801-581-6255



Lisa Reynolds, RN
Clinical Research Coordinator
University of Utah Medical Center
30 North 1900 East, 3B301
Salt Lake City, Utah 84132
801-585-0385



June 29th, 2005

Church of Christian Science
Second Church
1165 S Foothill Drive
Salt Lake City, Utah 84108

Dear Congregation,

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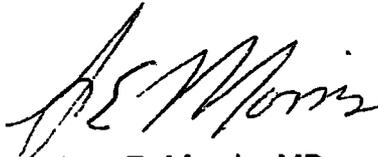
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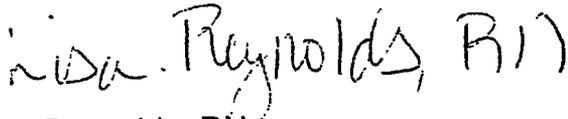
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Director of Trauma Services
University of Utah Medical Center
30 North 1900 East, 3B110
Salt Lake City, Utah 84132
801-581-6255



Lisa Reynolds, RN
Clinical Research Coordinator
University of Utah Medical Center
30 North 1900 East, 3B301
Salt Lake City, Utah 84132
801-585-0385



June 29th, 2005

Kingdom Hall
Jehovah's Witness, Salt Lake City Creek Congregation
1606 South 1000 West
Salt Lake City, Utah 84104

Dear Kingdom Hall,

University Hospital has been chosen to be one of few level one trauma centers to conduct a research study using PolyHeme[®], a blood substitute, to treat severely injured and bleeding patients. We feel it is important to inform you and other Kingdom Halls in the area of this research study because patients in this study will be randomized at the scene of injury to receive either PolyHeme (investigational treatment) or the standard of care (salt water and donated blood) without obtaining their informed consent to participate in the study. We take into strong consideration your beliefs and feel as though you should be informed about the study and how it works.

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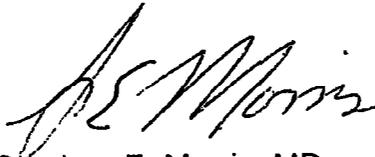
School of Medicine
Department of Surgery
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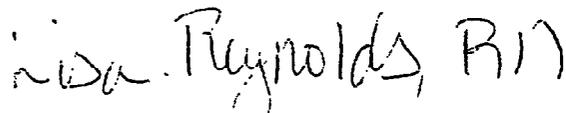
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30 North 1900 East, 3B110
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801-581-6255



Lisa Reynolds, RN
Clinical Research Coordinator
University of Utah Medical Center
30 North 1900 East, 3B301
Salt Lake City, Utah 84132
801-585-0385



June 29th, 2005

Kingdom Hall
Jehovah's Witness, Millcreek Congregation
2240 South 600 East
Salt Lake City, Utah 84106

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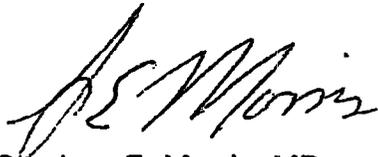
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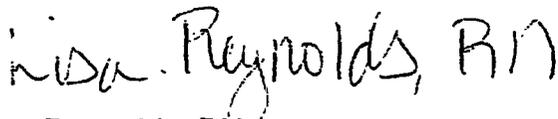
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