

## Community Consultations for Polyheme Trial

Three community meetings were held:

<u>Date</u>	<u>Time</u>	<u>Location</u>	<u>Number Completing Consultation Form</u>
12 July	1900	Live Oak	25
13 July	1830	Fort Sam Houston	101
19 July	1900	Converse	<u>24</u>
Total			150 Attendees

Note: Totals vary by question in accordance with how many answered that question.

### Race by Site

	<u>Blesse</u>	<u>Live Oak</u>	<u>Converse</u>	<u>Total</u>	<u>Percent</u>
Asian	1			1	1.0%
Black	16			16	15.7%
Caucasian	34	17	18	69	67.7%
Hispanic	13	1	1	15	14.7%
Native American	<u>0</u>	<u>1</u>	<u>1</u>	<u>1</u>	1.0%
	64	19	19	102	

### Age by Site

	<u>Blesse</u>	<u>Live Oak</u>	<u>Converse</u>	<u>Total</u>	<u>Percent</u>
18-40	50	3	6	9	53.6%
41-60	19	9	13	41	37.3%
≥61	<u>1</u>	<u>7</u>	<u>2</u>	<u>10</u>	9.1%
	70	19	21	110	

### Gender by Site

	<u>Blesse</u>	<u>Live Oak</u>	<u>Converse</u>	<u>Total</u>	<u>Percent</u>
Female	15	4	9	28	24.4%
Male	<u>57</u>	<u>18</u>	<u>12</u>	<u>87</u>	75.7%
	72	22	21	115	

Question #1: Understand study	99% yes
Question #2: Understand Subjects will not give consent	97% yes
Question #3: Object to Enrollment of Subjects without their prior consent:	34.4% Yes (n=145)
Question #4: Willing to allow study in community ("approval")	82% Yes (n=143)

**Approve (#4) By Site:**

Live Oak	95% Yes (n=22)
Fort Sam Houston	76% Yes (n=98)
Converse	96% Yes (n=23)
All Sites Combined	82% Yes (n=143)

**Approve (#4) By Sex:**

Female	100% Approved p=.03
Male	85.5% Approved

**Approve (#4) By Race:**

Asian	100% (n=1)
Black	87.5% (n=16)
Caucasian	92.5% (n=67)
Hispanic	80% (n=15)
Native American	100% (n=1)

**Approve (#4) By Age:**

18-40	82% (n=56)
41-60	92.5% (n=40)
>61	100% (n=10)

Consistency of Understanding and Approval Questions 1 & 4 (Responded yes to Question #1 and Question #4):

82% (n=141)

Consistency of Understanding and Objection (Rev) Questions 1 & 3 (Responded yes to Question #1 and no to Question #3):

62.3% (n=141)

Consistency of Question 3 Objection (Rev) and Question 4 Approve (Responded no to Question #3 and yes to Question #4):

80.9% (n=141)

# BAMC to join in testing of blood substitute

The nationwide study  
already includes  
University Hospital.

BY CINDY TUMIEL  
EXPRESS-NEWS STAFF WRITER

Badly injured patients flown to Brooke Army Medical Center may soon become part of an ongoing national study to test an experimental but potentially life-saving blood substitute.

Doctors at BAMC announced Monday that the military hospital is the second trauma center in the San Antonio area to join a clinical study of PolyHeme, an oxygen-carrying fluid that doctors say could help keep trauma victims from bleeding to death while they are being transported to a hospital.

University Hospital, the region's largest Level 1 trauma center, has been part of the study for more than a year.

Dr. Toney W. Baskin, an Army trauma surgeon, said BAMC should join the study within a month, as soon as military medical committees give the final approval.

Currently, ambulances cannot carry whole blood because it is perishable and must be properly matched to a patient.

Paramedics have only saline on board, and trauma patients can die if severe blood loss deprives the brain and other organs of vital oxygen, Baskin said.

If results with civilian accident victims are positive, the blood substitute could become part of the battlefield medic's kit one day, he said.

"It's a bridge," Baskin said of the blood substitute. "It will buy you time (until you get) to where blood might be available."

If you're on a mountaintop in Afghanistan, it would help save your life until you could get to a combat support hospital where there might be blood available."

Air Life helicopter personnel have been trained in the use of the substitute, and only patients transported by these ambulances will be potential study participants.

But most patients will be unconscious or too ill to make informed consent at the time they receive the blood substitute and join the study.

Because of this, BAMC and

## A substitute for blood

Brooke Army Medical Center will join University Hospital in a national study to evaluate PolyHeme, a blood substitute.

### What is PolyHeme?

An oxygen-carrying blood substitute compatible with all blood types, for use in urgent blood loss when whole blood is not immediately available.

### What will the study involve?

Paramedics at the scene of an accident or aboard a helicopter ambulance will provide badly injured patients either the standard of care, which is a saline solution, or a blood substitute until the patient arrives at the hospital.

### Why is it important?

Trauma victims often die from loss of blood. Whole blood is typically not available on ambulances or at the scene of an accident.

Source: BAMC HARRY THOMAS/STAFF

University doctors have had to conduct public outreach at community meetings and through the media to make people aware of the ongoing study.

The ethical considerations were one of the reasons why military doctors took longer to approve BAMC's participation, Baskin said.

"We wanted to be absolutely sure that we were doing this ethically and morally correct and by the letter of the law," Baskin said.

PolyHeme is manufactured by Northfield Laboratories in Evanston, Ill., one of a half-dozen companies trying to come up with products that can be infused into patients who have lost a large volume of blood.

University and BAMC hope to enroll 20 patients apiece, part of some 700 the manufacturer needs to enroll around the country.

Dr. Ronald Stewart, chief of trauma at University and the hospital's lead investigator for the study, said seven local patients have been enrolled so far.

No early results of the study have been disclosed, he said.

Individuals who do not want to participate can obtain a bracelet from University Hospital that will instruct paramedics not to administer the blood substitute in the event of an accident.

To learn more about the study or obtain a bracelet, call the project coordinator at (210) 587-8623.

ctumiel@express-news.net



## The IRB and Conduct of Research

- What is an IRB?
- Institutional Review Board
- Review and approve all experiments that involve human subjects
- Primary mission is the protection of human research subjects



## IRB



- IRB members appointed by hospital commander (BAMC) and Health Science Center President
  - Mostly doctors, but, at least:
    - 1 Non-scientific member
    - 1 Community member
 } Community volunteers
  - Gender, races represented; reasonable expertise
- IRB members NOT part of research team!



## IRB



- Approve, disapprove or modify research protocols
- Review all experiments yearly
- Make sure changes get made
- Suspend or terminate approval



## IRB



Three fundamental principles:

1. *Beneficence* - Appropriate risk/benefit ratio
2. *Justice* - Distribute risk and benefit fairly
3. *Respect for persons* - Informed consent



## *Beneficence*



- Appropriate risk/benefit ratio
- Maximize possible benefits and minimize possible harms
- Is there direct potential benefit to the patient?
- Is there benefit for society?



## *Justice*



- Distribute risk and benefit fairly
- Selection of research subjects unbiased
  - Elderly, children
  - Minorities
  - Prisoners
  - Socioeconomic status



## *Respect for Persons*



- Informed Consent - Giving patients an opportunity to decide
  - Information - Purpose of research, risks and benefits
  - Comprehension - Language that is easily understandable
  - Voluntary - Free of coercion and undue influence



## *Emergency Research*



- Patients not able to give informed consent
- Experiment needs to be started before legally authorized representative or next-of-kin can consent for the patient
- No way to identify eligible patients ahead of time



### *Federal Law Allows*



- Clinical Trial in Emergency Setting
- NO INDIVIDUAL CONSENT
- IRB Approval Required
- Community Consultation Required



### *Emergency Research*



- Life-saving situation
- Available treatments are unproven
- Collection of scientific evidence is necessary
- Allows a randomized, placebo-controlled experiment



### *Emergency Research*



- Direct potential benefit to patients
- Preclinical and animal studies have already been conducted
- Reasonable risks for patients



### *Charge to Audience*



- Listen
- Ask Questions
- Feedback (survey)

**PolyHeme® Study**  
**Dr. Tony Baskin, CCH, MC**

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 S.D.P. Injection [Polymerized Human Hemoglobin (Pyridoxylated), PolyHeme®] When Used to Treat Patients in Hemorrhagic Shock Following Traumatic Injuries Beginning in the Prehospital Setting

7:29 PM PolyHeme Study

**Study Purpose:**

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

7:30 PM PolyHeme Study

**Definitions**

- PolyHeme® – an experimental blood substitute being used in this study.
- Subject – Someone who is enrolled into a study.
- Trauma – a severe injury.

7:31 PM PolyHeme Study

**What does this mean to myself and the community?**

- Trauma victims could die from a large loss of blood -this is called hemorrhaging.
- Commonly, blood and blood products are not available at the scene of an accident.
- This study will provide an experimental blood product (PolyHeme®) at the scene of an accident.

7:32 PM PolyHeme Study

### What does this mean to myself and the community?

- If a trauma victim needs blood, PolyHeme® can be given up to 12 hours after injury.
- PolyHeme® is compatible with all blood types.

12/10

PolyHeme Study

### What happens after I am enrolled into the study?

- You or your family will be asked to allow you to continue in the study.
- You may choose to drop out of the study at anytime. This will not affect your care.
- The Research Nurse will keep in touch with you or your family to check on your well-being and to answer questions.

12/10

PolyHeme Study

### What happens if I am enrolled into the study?

- The Research Nurse will notify you and your family immediately of your enrollment into the study.
- Doctors will closely monitor and document your progress.

12/10

PolyHeme Study

### What happens after I am given PolyHeme®?

- You will have about 2 teaspoons of blood drawn almost everyday for the first 7 days.
- We will record your medical history.
- We will record any medications you are currently taking.
- None of the study procedures are added to the cost of your hospital stay.

12/10

PolyHeme Study

## What happens after I am enrolled into the study?

- A Research Nurse will check your condition for the first 7 days.
- You will be asked to come back to the hospital 30 days after your injury for a blood draw and check up.
- After you leave the hospital a Research Nurse will call you to make sure you are doing ok.

7/2007

PolyHeme Study

11

## Population

- Around the county a total of 720 subjects will be enrolled into the study.
- BAMC and University Hospital System will enroll 20 patients each.
- Everyone enrolled will not get PolyHeme ®.
- 50% of the subjects will get the normal treatment for their injury.

7/2007

PolyHeme Study

11

## What is PolyHeme ®?

- PolyHeme ® is a blood substitute that is filtered to remove everything except the particles that carry oxygen.
- Sterile IV fluid is added to the oxygen carrying particle to make PolyHeme ®.

7/2007

PolyHeme Study

11

## Your condition at the time of enrollment will mean you have all of the following:

- Severe trauma.
- Male or female >18 yrs.
- Large amount of blood loss due to injury.
- Systolic Blood pressure (the top number)  $\leq$  90 mmHg at the scene.

7/2007

PolyHeme Study

11

You will not be enrolled if you have any of the following conditions:

- Death is likely.
- Severe head injury.
- Need CPR or heart has stopped prior to starting PolyHeme®.
- Pregnant or suspected of being pregnant.
- Religious objection to blood.
- Known request to "Do Not Resuscitate".

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11

Questions?



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12

### Current Status

- Community Consultation is in process.
- Final review and approval after Community notification is completed.
- Patient enrollment may then begin.

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13

# **News US Army Institute of Surgical Research-Brooke Army Medical Center and University Hospital**

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Contact: 210-567-3623 for questions

## **Public invitation:**

**USAISR Brooke Army Medical Center and University Hospital, chosen to study blood substitute in trauma patients**

**WHAT: Please join us for a Community meeting about a research study to be conducted by USAISR, Brooke Army Medical Center and University Hospital.**

**WHEN: July 12, 2005 at 7:00 p.m.**

**WHERE: Live Oak Town Hall**

**WHEN : July 19, 2005 7:00p.m.**

**WHERE: Converse City Hall**

**WHEN : July 13, 2005 6:30 a.m.**

**WHERE: Blesse Auditorium, Army Medical Department Center and School, Fort Sam Houston, Texas**

**WHO: Toney W. Baskin, M.D. COL, MC, Principal Investigator USAISR-BAMC, Chief, Trauma Service BAMC will present the details of the study.**

**WHY: USAISR-BAMC will be among a group of Level I trauma centers in the country to study PolyHeme®, an oxygen-carrying blood substitute, and its potential ability to increase survival in critically injured and bleeding patients.**

**Treatment would begin before arrival at the hospital, either at the scene of the injury or in the air ambulance.**

Please come and learn more about this potential life saving drug and its effect on your community.

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## QUESTIONS AND ANSWERS POLYHEME® TRAUMA TRIAL

### **Why is this study being conducted?**

*To evaluate the life-saving potential of PolyHeme® when given to severely injured patients and bleeding patients, starting at the scene of injury  
To see if PolyHeme can save lives when given at the scene of an accident where a person is badly injured and bleeding.*

### **What is the title of this study?**

*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*

### **What is the design of this study?**

*Patients in "hemorrhagic shock" will begin to receive either the standard of care (salt water) (control) or PolyHeme (investigational treatment). Treatment would 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.*

*Patients are shock from bleeding will be put randomly into one of two groups.*

*"Randomly means they are put into the groups using a process like "flipping a coin". One group, called the "Control" group will get salt water and blood for the bleeding. The study group will get PolyHeme for the first 12 hours for the bleeding. Treatment begins at the scene of the injury or in ambulance and lasts for 12 hours.*

*In the hospital, patients in the control group will receive salt water for hydration and blood if necessary to boost oxygen levels. As much as needed is given.*

*Patients in the study group will receive salt water for hydration and PolyHeme® to boost oxygen levels. Up to 6 units PolyHeme will be given as needed during first 12 hours. After that, blood is given if needed.*

### **What is hemorrhagic shock?**

*Hemorrhagic means losing a lot of blood.*

*Shock is a life-threatening condition that might include:*

- *Dangerously low blood pressure*
- *Internal organs not getting enough oxygen and having trouble working well*
- *Dying if treatment doesn't work*

**Why is there a need to improve the way trauma patients are treated now?**

*Trauma is the leading cause of death among Americans under the age of 45.*

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

*They are given saline solution (salt water) at the scene or in the ambulance. When they arrive at the hospital, they are given blood. The person should receive his/her own blood type. This takes some time to do tests to be sure the right type of blood is given.*

**Who can take part in this 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 severe injuries causing lots of bleeding*

**Who would be excluded from the study?**

*Women who are obviously pregnant  
Patients with severe brain injuries  
Patients who require CPR to maintain their heartbeat  
Patients who are not likely to live because the injuries are so bad  
Patients who are known to object to blood transfusions  
Patients who are known to refuse CPR*

**What is PolyHeme®?**

*PolyHeme® is a blood substitute made from human blood that lets oxygen be carried to the cells in the body. PolyHeme can be given to people with any blood type. There is no special testing needed. PolyHeme® has been purified to reduce the risk of causing diseases. PolyHeme is good to use for up to 12 months after it is made.*

**Is PolyHeme® safe?**

*In clinical trials to date, PolyHeme® has demonstrated no clinically relevant adverse effects.  
Up to now, PolyHeme has not caused any clinically bad problems.*

*Past studies have shown that PolyHeme® carries as much oxygen as blood, has not caused problems for the body's organs, keeps people alive who have lost all of their own blood, and can be given up to two times a person's entire blood volume.*

**Has PolyHeme® been tested on humans before?**

*There have been 5 human clinical trials of PolyHeme®.*

### **How many patients have been treated with PolyHeme®?**

*Over 300 patients have been treated, including patients in a hospital-based trauma trial.*

### **What happened to them?**

*In the Phase II hospital trauma trial, PolyHeme® significantly increased survival compared with historical controls.*

*In a hospital based trauma study, PolyHeme greatly increased the survival rate as compared to the people with the same severity of injury who didn't get PolyHeme.*

### **What is an exception from informed consent?**

*Regulations established by the Federal government, (21 Code of Federal Regulations 50.24) specifies the conditions under which an exception from informed consent so that in emergency situations, research can be carried out even when consent is not possible because of the nature and extent of the patient's injuries.*

*The Federal regulations concerning research allow research studies to be done in life-threatening situation when a person cannot provide consent because they are too sick. This is called an "exception" because the informed consent does not need to be given before the study starts. However, as soon as the person can understand what is happening in the study, then it will be explained to them and he/she will have a chance to give permission to continue the study or can make the decision not to continue.*

### **Why was such an exception granted for this study?**

*Taking part in this study could directly benefit the person because:*

- *there is a life-threatening injury that needs to be treated right away*
- *Previous studies with PolyHeme showed that it helped people and reduced the problems that are caused by many blood transfusions*
- *the risks of using PolyHeme® are reasonable in relation to what is known about serious injuries involved and the risks and benefits of standard therapy*

*It is expected that people could not give informed consent because they are in shock*

*There won't be time to find and ask for consent from the patient's legally authorized representative (LAR) 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 patients don't want to take part in this study?**

*Patients can withdraw from the study at any time by notifying the investigator.*

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

*Patients will still receive the standard of care if they decide not to take part in this study.*

**What are the potential benefits of taking part in the study?**

*PolyHeme® may increase the chance of survival after a severe trauma injury.*

*Patients might avoid the risks of blood transfusion.*

*Patients might avoid problems with the body's organs that can happen after getting many blood transfusions*

*This study may help patients in the future.*

**What are the potential risks of taking part in the study?**

*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 take part in this study. The costs of certain laboratory tests that are required will be paid by the study sponsor.*

**Will patients get paid to be in the study?**

*No, patients will not be paid for being in this study.*

**Who is the manufacturer of PolyHeme®?**

*Northfield Laboratories Inc., Evanston, IL. For more information, visit [www.northfieldlabs.com](http://www.northfieldlabs.com)*

## News Release – BAMC/ISR has Joined The PolyHeme® Clinical Trial

Brooke Army Medical Center and the U.S. Army Institute of Surgical Research together will become the first military medical organization to conduct a clinical trial with a blood substitute product called PolyHeme®.

Researchers at 20 civilian medical centers around the country are conducting a Phase III clinical trial of PolyHeme®. The multi-center trial will involve an estimated 720 patients. Brooke Army Medical Center and the University of Texas Health Science Center in San Antonio together will enroll 40 participants – these two level 1 trauma centers cover the greater San Antonio area for trauma care.

Produced by Northfield Laboratories of Evanston, IL, PolyHeme® has shown promise in earlier trials. The product is intended to keep trauma victims alive during transport to a hospital where resuscitation fluids and blood transfusions are available to treat shock from blood loss.

Treatment will begin at the scene of injury and continue in the air ambulance to the hospital. Eligible patients will receive either standard of care intravenous fluid (containing salt water) or PolyHeme®. Because the patients eligible for the study are unlikely to be able to provide consent due to the extent and nature of their injuries, the trial will be conducted under federal regulations that allow clinical research in emergency settings using an FDA-approved exception from the requirement for informed consent.

Patients in hemorrhagic shock (a condition of dangerously low blood pressure due to blood loss) will begin to receive either the standard of care (salt water) or PolyHeme® (investigational treatment). Treatment would begin before arrival at the hospital, either at the scene of the injury or in the air ambulance, and continue during a 12-hour post-injury period in the hospital. In the hospital, patients in the control group will receive salt water for hydration and blood if necessary to boost oxygen levels.

If approved by the FDA, a blood substitute would be very valuable in treating hemorrhage on the battlefield when blood is not immediately available. Military doctors think an effective blood substitute product would save many lives in battlefield medicine.

## AGENDA FOR COMMUNITY MEETING

Live Oak Community Meeting

July 12, 2005 at 7:00 p.m.

### AGENDA

#### POLYHEME® TRAUMA TRIAL COMMUNITY MEETING

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

- 7:00 p.m. Registration
- 7:15 p.m. Welcome and Introductions
- 7:20 p.m. Federal regulations and the Institutional Review Board Dr. Jenice Longfield
- 7:30 p.m. Explanation of PolyHeme® trial Dr. Tony Baskin Primary Investigator
- 7:45 p.m. Questions and Answers Dr. Jenice Longfield & Dr. Tony Baskin
- 8:30 p.m. Adjourn

**FOR IMMEDIATE RELEASE**

**BROOKE ARMY MEDICAL CENTER  
AND THE UNIVERSITY OF TEXAS  
ARE PARTICIPATING IN A STUDY FOR AN INVESTIGATIONAL  
BLOOD  
SUBSTITUTE IN TRAUMA PATIENTS**  
*Clinical Study: Treatment to Begin at Scene of Injury*

San Antonio, Texas -- July 7, 2005 —BAMC and University Hospital are participating in a groundbreaking national clinical trial to evaluate the safety and efficacy of PolyHeme®, an oxygen-carrying blood substitute, in increasing survival of 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 air ambulance, and continue during a 12- hour post injury period in the hospital. Since blood is not presently carried in ambulances, the use of PolyHeme® in these settings has the potential to address a critical unmet medical need for an oxygen-carrying solution where blood is currently not available. 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.

“We are excited to be included in this groundbreaking clinical trial,” commented Tony Baskin, M.D., the principal investigator. “Trauma-related injuries are a leading cause of death among Americans under 45 years old, according to the CDC’s National Center for Injury Prevention and Control. In fact, almost one in five trauma patients die from their injuries. If we can begin to treat these patients very early with an oxygen-carrying solution and keep their hemoglobin levels up, we might well see more survivors,” he added.

Because the patients eligible for this study are unlikely to be able to provide prospective informed consent due to the extent and nature of their injuries, the study will be conducted under federal regulations that allow for clinical research in emergency settings using an exception from the requirement for informed consent (21 CFR 50.24).

Use of this provision in a study protocol is granted by the Institutional Review Board (IRB) responsible for approval of the research study if the IRB finds that patients are in a life-threatening situation requiring emergency medical intervention, currently available treatments are unsatisfactory, potential risks are reasonable, and participation in the study could provide a direct benefit to the patients enrolled

The treatment under study, PolyHeme®, is a universally compatible, immediately available, oxygen-carrying resuscitative fluid designed for use in urgent blood loss when blood is not immediately available. It has been studied extensively in trauma trials in the hospital setting. PolyHeme® is manufactured by Northfield Laboratories Inc., of Evanston, Illinois.

**About Northfield Laboratories**

Northfield Laboratories is a developer of an oxygen-carrying blood substitute. Its product, PolyHeme® requires no cross matching, making it immediately available and compatible with all blood types, and has an extended shelf life of over 12 months.

**US Army Institute of Surgical Research  
and  
Brooke Army Medical Center  
POLYHEME® TRAUMA STUDY  
PUBLIC NOTICE**

USAISR and BAMC operate as a Level I trauma center in the United States and are considering participating in a clinical study of a new, potentially life-saving treatment for severely injured patients who are bleeding and in shock. **A prerequisite for participating in this study is notification to the community of a waiver of informed consent.**

The traditional approval of a clinical trial includes a requirement that informed consent be obtained from patients before enrollment can occur. Under special circumstances and in accordance with federal regulations, a clinical trial may enroll subjects in emergency situations without informed consent if the community is given notice first.

In the proposed trial, patients over 18 years of age who are severely injured, bleeding and in shock will be eligible to be enrolled in the trial.

In severely injured trauma patients it is unlikely to be able to obtain informed consent due to the nature and extent of the injuries. This study uses a provision for an exception from informed consent requirements in accordance with federal regulations (21 CFR 50.24) Patients, their legally authorized representative, or a family member will be notified at the earliest opportunity of their enrollment and the details of the research study. A patient may withdraw or be withdrawn from the study at any time without influencing the care he or she would receive and without penalty or loss of benefits to which the patient is otherwise entitled.

Any person who has questions, comments or wishes not to participate in this study may contact 210-567-3623.