

**Minutes record – CCPD**  
**RTBSE-11-1**  
**COMIRB # 03-229**

Following a brief power point presentation by Dr. E.E. Moore, community members raised the following points:

Multiple questions were asked, primarily focusing on specifics of the product and study itself e.g., is study blinded? What is shelf life of PolyHeme? How is it carried on the ambulance? What are the risks? Explain the virus risk? Will patients be notified that they were enrolled? What is our experience? Does hemoglobin breakdown like red blood cells? Additionally, one community member recommended that we address the African-American community specifically (which we intend to do) and solicited each of the community board members to disseminate this information to other community organizations, and to offer that we attend other community meetings if they request that we do. Dr. Moore responded that this was a fantastic idea, and that we'd be willing to speak to anyone that wanted to listen.

Meeting Date and Time: **Thursday May 29, 2003**

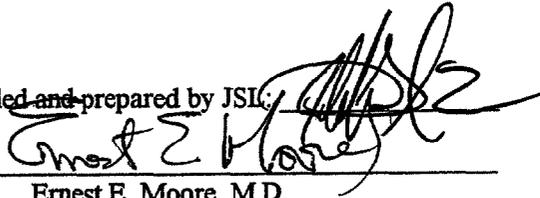
Group: **Denver Community Health Board**

Meeting Location: **660 Bannock, Fifth Floor Administrative Board Room**

Duration of meeting: **Approximately 35 minutes**

Investigator assessment: **Positive**

Minutes recorded and prepared by JSIC

P.I. Signature: 

Ernest E. Moore, M.D.

Sign in Sheet

Study RTBSE-11-1 - PolyHeme

COMIRB # 03-229

Denver Community Health Board

29-MAY-03

No.	Name	Organization / Interest
1	Renée L. Cisneros	Board Member
2	Al Nesprin	Board member OCHS
3	Judy NAOMI	CHS Administrator
4	Beth Lindross	DH CHS Admin
5	Paul Yanderf	Board member
6	CONSTANCE Eberhardt	Board member
7	Kenneth Floyd	visitor
8	E. Dean Proctor	BOARD MEM
9	<del>Rosario P. de Baca</del> ROSARIO P. de Baca	Board Member
10	Ti Swanson	Board Member
11	Rose Chavez	Board member
12	IZORA Deltzman	Board member
13	Richard Wright	<del>Richard Wright</del> DH/CHS
14	Jennifer Cavarra	DH / Community Health
15	JOE MASI	DH - INTEGRITY OFFICER
16	PAT DEARMEY	DH - INTERNAL AUDITOR
17	Chris Colwell	Emergency Physician, EMS medical Director
18	JIM HAENEL	SURGERY
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**FEEDBACK FORM FOR PARTICIPANTS**  
**RTBSE-11-1 - PolyHeme®**  
**COMIRB # 03-229**

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 the investigators?

*I suggest that keep records of health of people that have received Polyheme for at least 10 years to check on infection potential*

Age: 71      Ethnic background: Caucasian

Gender: Male  Female

Thank you for your participation today.  
Please contact Jeff Long at 303-436-7906 or [Jeff.Long@dhha.org](mailto:Jeff.Long@dhha.org)  
if you have any other questions.  
Or go to [www.denverhealth.org](http://www.denverhealth.org) and click on "Physician Research"

(<http://www.denverhealth.org/TraumaCenter/Polyheme.aspx>)

**FEEDBACK FORM FOR PARTICIPANTS**  
**RTBSE-11-1 - PolyHeme®**  
**COMIRB # 03-229**

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 the investigators?

What's the cost and how will it be paid for?  
Great presentation! Clear answers to questions. --  
Good job.

Age: 54                  Ethnic background: Caucasian

Gender: Male  Female

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if you have any other questions.  
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(<http://www.denverhealth.org/TraumaCenter/Polyheme.aspx>)

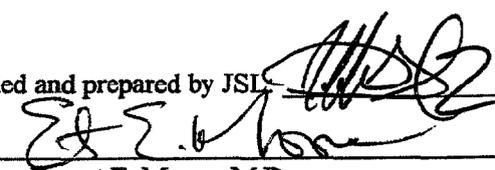
**Minutes record – CCPD**  
**RTBSE-11-1**  
**COMIRB # 03-229**

Following a brief power point presentation by Dr. Jeffrey L. Johnson, community members raised the following points:

Multiple questions asked: Q: How does this affect other blood types? A: There is no effect, all patients can receive this product irrespective of their blood type because the product contains no cell (membrane) which is where the specific antigens are found. Q: Is this considered "synthetic?" A: No – it is a human product. Q: Will it be given to patients who will only be admitted to DHMC? Q: Yes, in Denver. Q: If a patient has a reaction or dies, how will you (we) ascertain whether or not it was related to the product or the process of developing the product? A: That's why we're doing the trial. It will be based on a comparison of the experimental and control groups, both by the DSMB and at the end of the trial. Plus remember, hundreds of patient's have already received this product using informed consent so we do know what to expect. Q: How long is the shelf life? A: 18 months if refrigerated, approximately 30 days at room temperature, and a week in extreme heat (> 42 degrees Celsius). Q: What is the time frame for Community Consultation and start of trial? A: Unknown, depends on community response and IRB. We'll spend as much time as necessary, but are hoping to begin patient enrollment late July. Q: How long does product stay in body? A: Approximately 48 hours – completely eliminated in 72 hours. Q: Are there any competing products? A: Two other products, no one in trauma. Q: Is there any known adverse effect in patients with substance abuse problems? A: No Q: Are you (we) concerned about lawsuits related to this research? A: No. In 171 patients over nine years there hasn't been any lawsuits. Q: Is this trial approved by the FDA? A: Yes. Q: If patients die, how do you know it was related to trauma as opposed to the product? What if a patient has pre-existing hypertension or renal problems? A: Again, that's why we have the DSMB Q: How do you (we) identify patients with pre-existing medical conditions? A: Impossible unless they have something to identify that (e.g. medic alert bracelet).

Meeting Date and Time: **Tuesday June 10, 2003**  
Group: **Downtown Denver Residents Organization**  
Meeting Location: **511 16th Street Suite 200**  
  
Duration of meeting: **Approximately seventy-five minutes**  
  
Investigator assessment: **Overall, positive. One hostile response.**

Minutes recorded and prepared by JSI

P.I. Signature: 

Ernest E. Moore, M.D.

## Sign In Sheet

Study RTBSE-11-1 - PolyHeme

COMIRB# 03-229

Downtown Denver Residents Organization

10-JUN-03

No.	Name	Organization / Interest
1	JANE WALLACE	DDRO
2	Arlene Parker	DDRO
3	Mauritha Everett	University of Colorado
4	John Maslanik	DDRO - Pres.
5	Stee Ryeer	DDRO - VP.
6	Jenny Salimi	DDRO
7	Ellie Jensen	COMIRB - UCHSC
8	EMILY HOPKINS	COMIRB - UCHSC
9	Lisa Jensen	U. of Colorado Health Sciences Center
10	Chris Colwell	Denver Health
11	Jim HAENEL	DHMC
12	Dave Mooney	DDRO - MKTG
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**FEEDBACK FORM FOR PARTICIPANTS**  
**RTBSE-11-1 - PolyHeme®**  
**COMIRB # 03-229**

Downtown Denver Residents Organization  
June 10, 2003

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 the investigators?

Wrong on Not - I trust that you are trying to  
do the right thing for people

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Age: 46          Ethnic background: WASP

Gender:  Male          Female

Thank you for your participation today.  
Please contact Jeff Long at 303-436-7906 or Jeff.Long@dhha.org  
if you have any other questions.  
Or go to [www.denverhealth.org](http://www.denverhealth.org) and click on "Physician Research"

(<http://www.denverhealth.org/TraumaCenter/Polyheme.aspx>)

**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

Downtown Denver Residents Organization

June 10, 2003

*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 I have too many allergies

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 the investigators?

Narrow down a risk group  
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Age: 26

Ethnic background: White/Cauc:

Gender: Male  Female

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**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

Downtown Denver Residents Organization

June 10, 2003

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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 the investigators?

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Age: 48      Ethnic background: White

Gender:    Male     Female

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**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

Downtown Denver Residents Organization

June 10, 2003

*Please circle your answers*

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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 the investigators?

NO

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Age: 52

Ethnic background: CAUCASIAN

Gender: Male  Female

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**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

Downtown Denver Residents Organization

June 10, 2003

*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 the investigators?

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Age: 46

Ethnic background: White

Gender: Male  Female

Thank you for your participation today.  
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**FEEDBACK FORM FOR PARTICIPANTS**  
**RTBSE-11-1 - PolyHeme®**  
**COMIRB # 03-229**

Downtown Denver Residents Organization  
June 10, 2003

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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 the investigators?

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Age: 39      Ethnic background: HISPANIC

Gender: Male       Female

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**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

Downtown Denver Residents Organization

June 10, 2003

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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 the investigators?

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Age: 51      Ethnic background: CAUCASIAN

Gender: Male  Female

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*(<http://www.denverhealth.org/TraumaCenter/Polyheme.aspx>)*

**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

Downtown Denver Residents Organization

June 10, 2003

*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 the investigators?

*Due to med problems & medications  
we wouldn't be good study subjects*

Age: 58

Ethnic background: Caucasian

Gender: Male

Female

Thank you for your participation today.

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**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

Downtown Denver Residents Organization  
June 10, 2003

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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 the investigators?

Good luck to all of you and  
Thanks!

Age: \_\_\_\_\_

Ethnic background: Caucasian

Gender: Male \_\_\_\_\_

Female

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(<http://www.denverhealth.org/TraumaCenter/Polyheme.aspx>)

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**RTBSE-11-1 - PolyHeme®**  
**COMIRB # 03-229**

Downtown Denver Residents Organization  
June 10, 2003

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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 the investigators?

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Age: \_\_\_\_\_

Ethnic background: African American

Gender: Male \_\_\_\_\_

Female

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*(<http://www.denverhealth.org/TraumaCenter/Polyheme.aspx>)*

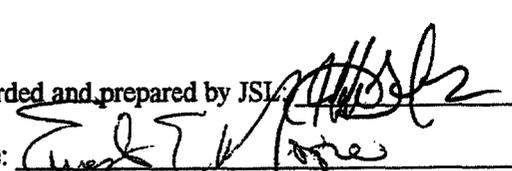
**Minutes record – CCPD**  
**RTBSE-11-1**  
**COMIRB # 03-229**

Following a brief power point presentation by Dr. Ernest E. Moore, community members raised the following points:

Q: How much will this product cost, and when will it be available? A: Unknown if or when it will be available. Also, cost is unknown but we believe the cost will be comparable to a unit of blood (\$250.00). Q: What are the storage requirements? A: For this trial, the storage requirements are the same as blood (kept refrigerated). Product is stable for 18 months if refrigerated, one month at room temperature and up to a week in extreme heat. If patients in the control arm need blood, will they be required to provide consent? A: No. Q: Are there any (pre-existing) conditions that patients may have that would interact adversely with PolyHeme? A: Not that we're aware of. Q: How long is the half life and how does product interact with blood? A: The half-life is approximately 24 hours, and it is metabolized the same way as blood. Q: Is there indication for product outside of trauma? A: Yes potentially, though trauma is the application the company is pursuing. The FDA is concerned about the potential for off label use. How many patients are admitted to the hospital from trauma? A: Over the last three years, 189 patients were admitted that met the criteria for this study. Only 146 of those were transported by Denver Health Paramedics. Q: Will Jehovah's Witnesses use this product? A: Many have, and in fact the study sponsor received a call almost every day from institutions nation wide requesting Polyheme for Jehovah's Witnesses. Additionally the "Watchtower" issued a statement that it is up to the individuals conscience as to whether or not they'll accept this type of product.

Meeting Date and Time: June 11, 2003 at 4:30PM  
Group: Denver Health Foundation  
Meeting Location: 660 Bannock Street  
Duration of meeting: Approximately 45 minutes  
Investigator assessment: Positive

Minutes recorded and prepared by JSL

P.I. Signature: 

Ernest E. Moore, M.D.

Sign In Sheet

Study RTBSE-11-1 - PolyHeme

COMIRB# 03-229

Denver Health Foundation

~~10 JUN 03~~ JUNE 11, 2003

(5)

No.	Name	Organization / Interest
1.	Evan Markovsky	Denver Health Foundation
2	STEPHEN B CLARK	DENVER HEALTH FND.
3	Frank J. Mooney	Denver Health
4	Jeanne Robb	Denver Health Foundation
5	K.K. Ciruli	Denver Health Foundation
6	Terry Schokts	Denver Health Fd.
7	Hugh J. McCleary	"
8	Gene Copeland	"
9	Anita Wesley	"
10	Mark Bandt	"
11	DAVID McREYNOLDS	"
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**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

~~Downtown Denver Residents Organization~~

<sup>2</sup> DENVER HEALTH FOUNDATION

~~June 10, 2003~~

6/11/03

Please circle your answers

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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 the investigators?

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Age: 44      Ethnic background: IRISH

Gender: Male       Female

Thank you for your participation today.  
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**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

Downtown Denver Residents Organization

June 10, 2003

② DENVER HEALTH FOUNDATION

6/11/03 ②

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 the investigators?

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Age: 58 Ethnic background: White

Gender: Male  Female

Thank you for your participation today.  
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Or go to [www.denverhealth.org](http://www.denverhealth.org) and click on "Physician Research"

(<http://www.denverhealth.org/TraumaCenter/Polyheme.aspx>)

All information obtained will be utilized solely for the purpose of documentation of the community consultation portion of the above referenced study, and specific information will remain in confidential, to be shared only with affiliated entities.

**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

~~Downtown Denver Residents Organization~~

~~June 10, 2003~~

① DEN. HEALTH FOUNDATION

6/11/03 ②

*Please circle your answers*

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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 the investigators?

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Age: 70      Ethnic background: White

Gender: Male  Female

Thank you for your participation today.  
Please contact Jeff Long at 303-436-7906 or Jeff.Long@dhha.org  
if you have any other questions.  
Or go to [www.denverhealth.org](http://www.denverhealth.org) and click on "Physician Research"

(<http://www.denverhealth.org/TraumaCenter/Polyheme.aspx>)

**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

Downtown Denver Residents Organization

DENVER HEALTH FOUNDATION

June 10, 2003

JUNE 11, 2003

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 the investigators?

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Age: 38

Ethnic background: ~~Hispanic~~ White

Gender: Male  Female

Thank you for your participation today.  
Please contact Jeff Long at 303-436-7906 or Jeff.Long@dhha.org  
if you have any other questions.  
Or go to [www.denverhealth.org](http://www.denverhealth.org) and click on "Physician Research"

(<http://www.denverhealth.org/TraumaCenter/Polyheme.aspx>)

All information obtained will be utilized solely for the purpose of documentation of the community consultation portion of the above referenced study, and specific information will remain in confidential, to be shared only with affiliated entities.

**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

Downtown Denver Residents Organization

June 10, 2003

①

DEN. HEALTH FOUNDATION

6/10/03 ②

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 the investigators?

Excellent Presentation - makes sense

Age: 58      Ethnic background: Caucasian

Gender: Male       Female

Thank you for your participation today.  
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**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

~~Downtown Denver Residents Organization~~

~~June 10, 2003~~

② DENVER HEALTH FOUNDATION

② 6/18/03

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 the investigators?

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Age: 33      Ethnic background: Caucasian

Gender: Male       Female

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**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

~~Downtown Denver Residents Organization~~ (10)

~~June 10, 2003~~ 6/14/03 (20)

DENVER HEALTH FOUNDATION

*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 the investigators?

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Age: 58 Ethnic background: \_\_\_\_\_

Gender: Male  Female \_\_\_\_\_

Thank you for your participation today.  
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Or go to [www.denverhealth.org](http://www.denverhealth.org) and click on "Physician Research"

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**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

~~Downtown Denver Residents Organization~~

~~June 10, 2003~~

6/11/03

DENVER HEALTH FOUNDATION

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 the investigators?

Great work.

Age: 52 Ethnic background: White

Gender: Male X Female \_\_\_\_\_

Thank you for your participation today.  
Please contact Jeff Long at 303-436-7906 or Jeff.Long@dhha.org  
if you have any other questions.  
Or go to [www.denverhealth.org](http://www.denverhealth.org) and click on "Physician Research"

(<http://www.denverhealth.org/TraumaCenter/Polyheme.aspx>)

**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

~~Downtown Denver Residents Organization~~

~~June 10, 2003~~

*6/11/03* **DENVER HEALTH FOUNDATION**

*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 the investigators?

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Age: 64

Ethnic background: W

Gender: Male  Female

Thank you for your participation today.

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*(<http://www.denverhealth.org/TraumaCenter/Polyheme.aspx>)*

**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

~~Downtown Denver Residents Organization~~

DENVER HEALTH FOUNDATION

June 10, 2003

6/10/03

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 the investigators?

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Age: 55

Ethnic background: \_\_\_\_\_

Gender: Male \_\_\_\_\_ Female

Thank you for your participation today.

Please contact Jeff Long at 303-436-7906 or Jeff.Long@dhha.org if you have any other questions.

Or go to [www.denverhealth.org](http://www.denverhealth.org) and click on "Physician Research"

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**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

~~Downtown Denver Residents Organization~~

~~June 10, 2003~~

DENVER HEALTH FOUNDATION

6/11/03

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 the investigators?

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Age: 55      Ethnic background: \_\_\_\_\_

Gender: Male \_\_\_\_\_ Female

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(<http://www.denverhealth.org/TraumaCenter/Polyheme.aspx>)

**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

~~Downtown Denver Residents Organization~~  
June 10, 2003

~~60~~ DENVER HEALTH FOUNDATION

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 the investigators?

Important work being done here - potential  
to save many lives.

Age: 55      Ethnic background: Caucasian

Gender: Male       Female

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if you have any other questions.  
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(<http://www.denverhealth.org/TraumaCenter/Polyheme.aspx>)

**Minutes record – CCPD**  
**RTBSE-11-1**  
**COMIRB # 03-229**

Following a brief power point presentation by Dr. Ernest E. Moore, community members raised the following points:

Q: Was PolyHeme used in the war? A: That's unknown at this point, though it was considered. Q: Is there a concern with regards to patients who may have pre-existing hypertension who get PolyHeme? A: Is a consideration, but again, we've not seen that affect with PolyHeme. Q: Is it safe for patients with Sickle Cell Anemia? A: Has not been looked at specifically. (A discussion ensued about a recent report in "Transfusion" [scientific journal] and it was reported as life saving in that article. The article was subsequently provided to this board member). Q: Has there been any long term follow up with regard to any "synthetics" left over in the body? A: Not specifically though we have confirmed that there is no organ dysfunction associated with the use of PolyHeme and it is removed from the body (metabolized) within 72 hours. Plus there are no "synthetics" in PolyHeme. Q: What happens when a patient becomes aware enough to provide consent? A: Described our plan to contact family / LAR as well as plan to give patient option to withdraw. Q: Do you (we) have experience with waiver from informed consent? A: Not using PolyHeme, all previously enrolled patients provided informed consent. However there have been trials utilizing the waiver. Q: Does PolyHeme have to be type and crossmatched? A: No. Q: Is there a problem with giving PolyHeme to patients with pre-existing diabetes? A: Not that we're aware of. Q: How is PolyHeme stored? Does it have to be refrigerated? A: If refrigerated it has a shelf life of 18 months. At "room temperature" it lasts 30 days and in extreme heat (>42 degrees Celsius) it lasts one week. Q: Is it already being carried in ambulances? A: No – Not until if and when study is approved. Q: When will the study be approved? A: Unknown. Q: After 18 months of storage, can it be used (reprocessed) or does it have to be discarded? A: Unknown. Q: Will PolyHeme replace blood? A: No – It only lasts 72 hours and if patient still need blood transfusion they'd likely get it at that time, though it may decrease the need for stored blood.

Dr. Moore asked for recommendation of other groups for us to meet with, and encouraged group to disseminate information and contact us for additional meetings.

Meeting Date and Time: Thursday, June 12, 11:30 a.m.

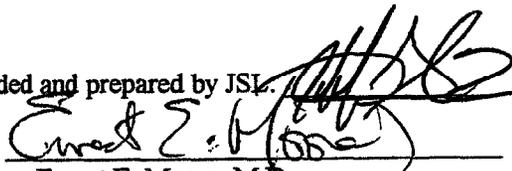
Group: Denver Health Multi Cultural Committee

Meeting Location: Gipson Eastside Family Health Center - 501 28th Street

Duration of meeting: Approximately one hour

Investigator assessment: Positive

Minutes recorded and prepared by JSL.

P.I. Signature: 

Ernest E. Moore, M.D.

Sign In Sheet

Study RTBSE-11-1 - PolyHeme

COMIRB# 03-229

~~Downtown Denver Residents Organization~~ MULTI CULTURAL COMMITTEE

~~JUN 03~~ JUNE 12, 2003

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- 10

No.	Name	Organization / Interest
29	DAN W. Buell	DHA
30	Eric [unclear]	CCD
31	David [unclear]	Catholic Charities
32	Hilli [unclear]	Denver Indian Family Resource Ctr
33	Bessie [unclear]	EDPHE
34	Beau [unclear]	CCAD
35	Queen A. [unclear]	DPS - Denver Public Schools
36	Rosie [unclear]	LARASA
37	Julie [unclear]	DHA
38	Benny Samuels	DH Community Voices
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**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

Downtown Denver Residents Organization  
June 10, 2003

MULTICULTURAL COMM. *6/12*

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 the investigators?

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Age: 49      Ethnic background: Latina

Gender: Male       Female

Thank you for your participation today.  
Please contact Jeff Long at 303-436-7906 or Jeff.Long@dhha.org  
if you have any other questions.  
Or go to [www.denverhealth.org](http://www.denverhealth.org) and click on "Physician Research"

(<http://www.denverhealth.org/TraumaCenter/Polyheme.aspx>)

**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

Downtown Denver Residents Organization

June 10, 2003

*Please circle your answers*

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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 the investigators?

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Age: 53      Ethnic background: Hispanic

Gender: Male  Female

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**FEEDBACK FORM FOR PARTICIPANTS**  
**RTBSE-11-1 - PolyHeme®**  
**COMIRB # 03-229**

Downtown Denver Residents Organization  
June 10, 2003

*Please circle your answers*

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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 the investigators?

*Long range - (time) affects - residue left in  
body that we may not be aware of  
at this time -*

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Age: 51      Ethnic background: American Indian  
Gender: Male       Female

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**FEEDBACK FORM FOR PARTICIPANTS**  
**RTBSE-11-1 - PolyHeme®**  
**COMIRB # 03-229**

Downtown Denver Residents Organization  
June 10, 2003

*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 the investigators?

VERY exciting study.

Age: 60                      Ethnic background: American Indian

Gender: Male \_\_\_\_\_ Female X

Thank you for your participation today.  
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**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

Downtown Denver Residents Organization

June 10, 2003

*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 the investigators?

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Age: 34

Ethnic background: African American / Hispanic

Gender: Male

Female

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(<http://www.denverhealth.org/TraumaCenter/Polyheme.aspx>)

**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

Downtown Denver Residents Organization

June 10, 2003

*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 the investigators?

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Age: 58

Ethnic background: African American

Gender: Male      Female X

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**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

Downtown Denver Residents Organization  
June 10, 2003

*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 the investigators?

I wish all Denver ambulances would carry this product. Most likely  
Denver Health would not be the ones picking up me or my loved ones.

Age: 32                      Ethnic background: Anglo

Gender: Male \_\_\_\_\_ Female

Thank you for your participation today.  
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if you have any other questions.  
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**FEEDBACK FORM FOR PARTICIPANTS**

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**COMIRB # 03-229**

Downtown Denver Residents Organization

June 10, 2003

*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 the investigators?

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Age: 53

Ethnic background: g/w - American

Gender: Male

Female

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**(<http://www.denverhealth.org/TraumaCenter/Polyheme.aspx>)**

**FEEDBACK FORM FOR PARTICIPANTS**  
**RTBSE-11-1 - PolyHeme®**  
**COMIRB # 03-229**

Downtown Denver Residents Organization  
June 10, 2003

*Please circle your answers*

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Yes      No

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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 the investigators?

No.

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Age: 57      Ethnic background: Caucasian

Gender: Male       Female

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(<http://www.denverhealth.org/TraumaCenter/Polyheme.aspx>)

**Minutes record – CCPD**  
**RTBSE-11-1**  
**COMIRB # 03-229**

Following a brief power point presentation by Jeffrey S. Long, RRT, community members raised the following points:

Q: Is Northfield Labs a publicly held company? A: Yes Q: Why has it taken so long to get to this point? A: Enrollment has been much slower secondary to the informed consent process in previous patients. Q: Is there any chance this will ever be available to children? A: Probably, but as with most drugs, it won't be looked at until if and when it's approved for adults. There are no plans for that at the current time. Q: Has PolyHeme been used to treat Auto Immune Hemolytic Anemia. A: Not that I'm aware of- It has been used to treat at least one patient with Sickle Cell Anemia and Acute Chest Syndrome (Described article published in Transfusion). Q: Will Jehovah's Witnesses accept it? A: They are allowed to by "The Watchtower" it's based on their personal conscience. Q: What other hospitals are participating? A: I don't know Q: Can elective surgery patients request PolyHeme? A: No – There have been clinical trials in elective surgery but this is specifically for trauma. Q: When will it be approved by the FDA? A: Unknown if or when it will be approved. Q: Has it been sent to Europe for testing? A: No. Q: When patients got hypertensive from earlier forms of blood substitutes, how long did it last? A: I don't know. Q: Any problem with giving PolyHeme to patients who have underlying disease? A: We don't think so, but that's why we're doing the study. To see if it's both safe and effective. Q: Is it on ambulances now? A: No – Not until (if) approved by the IRB. Q: Can we request for our family members to get PolyHeme if their in need of blood? A: No. It will only be available to trauma patients treated by Denver health EMS.

Encouraged to tell others and to contact for further information or to request additional meetings.

Meeting Date and Time: Wednesday, June 18, 12:00 p.m.

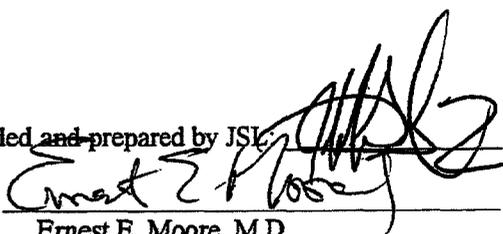
Group: Respiratory Therapy Students – Pima Medical Institute

Meeting Location: Pima Medical Institute - Samuel Building  
7290 W 72<sup>nd</sup> St, Denver

Duration of meeting: Approximately one hour

Investigator assessment: Positive

Minutes recorded and prepared by JSL

P.I. Signature: 

Ernest E. Moore, M.D.

## Sign In Sheet

Study RTBSE-11-1 - PolyHeme

COMIRB# 03-229

Pima Medical Institute

18, June 2003

No.	Name	Organization / Interest
1	Deanette Eufhar	Deanette.2004@yahoo.com
2	ERIKA BOOTH	Erikapilar@aol.com
3	Geri Ann Gunderson	- no email
4	JOSHUA ROJAS	joshua@hotmai.com
5	Naimi Vial	Familia Vial 296@aol.com
6	Soragie Smith	Soragie_Smith@hotmail.com
7	GENIVERE VALDEZ	GENIV33@AOL.COM
8	Laura Connerugh	- NO email
9	Melissa Richardson	Minilmt@MSU.COM
10	Amanda White	vinh-14@hotmail.com
11	Hailey Swanson	Haileychristine@aol.com
12	Stephanie Zoleta	<del>PRINCESSAZ</del> PRINCESSAZ@AOL.COM
13	Susan Auster	PGACOLO@aol.com
14	Debbie Griffin	dgriffin827@hotmail.com
15	Linsey Lomas	llomas@hotmail.com
16	Aimee Huerta	00hsmiles@aol.com
17	JAMES TODD	NO EMAIL
18	Sandra Blackman	sblackman77@netscape.net
19	Janice Hill	Junwd@aol.com
20	Shannon Jackson	rjackson7030@msn.com
21	Heidi Elmore	heidijoelmore@hotmail.com
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Sign In Sheet

Study RTBSE-11-1 - PolyHeme

COMIRB# 03-229

Pima Medical Institute

18, June 2003

No.	Name	Organization / Interest
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**FEEBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

Pima Medical Institute

June 18, 2003

*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 the investigators?

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Age: \_\_\_\_\_ Ethnic background: \_\_\_\_\_

Gender: Male \_\_\_\_\_ Female \_\_\_\_\_

Thank you for your participation today.

Please contact Jeff Long at 303-436-7906 or [Jeff.Long@dhha.org](mailto:Jeff.Long@dhha.org)  
if you have any other questions.

Or go to [www.denverhealth.org](http://www.denverhealth.org) and click on "Physician Research"

*(<http://www.denverhealth.org/TraumaCenter/Polyheme.aspx>)*

**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

Pima Medical Institute  
June 18, 2003

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Yes       No

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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 the investigators?

Great presentation, very informative!

Age: 22

Ethnic background: white

Gender: Male

Female

Thank you for your participation today.

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**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

Pima Medical Institute

June 18, 2003

Please circle your answers

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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 the investigators?

It would be great & even  
better if it were available to  
children. Due to the fact that  
they are the ones who suffer  
the most traumas

Age: 26

Ethnic background: Hispanic

Gender: Male  Female

Thank you for your participation today.

Please contact Jeff Long at 303-436-7906 or Jeff.Long@dhha.org  
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**COMIRB # 03-229**

Pima Medical Institute

June 18, 2003

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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 the investigators?

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Age: 26

Ethnic background: HISpanic

Gender: Male  Female

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**COMIRB # 03-229**

Pima Medical Institute

June 18, 2003

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Yes       No

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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 the investigators?

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Age: 34

Ethnic background: Hispanic

Gender: Male

Female

Thank you for your participation today.

Please contact Jeff Long at 303-436-7906 or [Jeff.Long@dhha.org](mailto:Jeff.Long@dhha.org) if you have any other questions.

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Pima Medical Institute

June 18, 2003

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Yes       No

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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 the investigators?

Amazing product.  
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Age: 20      Ethnic background: White

Gender: Male \_\_\_\_\_ Female

Thank you for your participation today.  
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if you have any other questions.  
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**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

Pima Medical Institute

June 18, 2003

*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 the investigators?

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Age: 36

Ethnic background: W

Gender: Male  Female

Thank you for your participation today.  
Please contact Jeff Long at 303-436-7906 or [Jeff.Long@dhha.org](mailto:Jeff.Long@dhha.org)  
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**COMIRB # 03-229**

Pima Medical Institute

June 18, 2003

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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 the investigators?

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Age: 40

Ethnic background: Cauc.

Gender: Male  Female

Thank you for your participation today.  
Please contact Jeff Long at 303-436-7906 or [Jeff.Long@dhha.org](mailto:Jeff.Long@dhha.org)  
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Pima Medical Institute

June 18, 2003

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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 the investigators?

The benefits of this trial are  
excellent  
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Age: 29      Ethnic background: Caucasian

Gender: Male \_\_\_\_\_ Female

Thank you for your participation today.  
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Pima Medical Institute

June 18, 2003

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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 the investigators?

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Age: 28

Ethnic background: Caucasian

Gender: Male  Female

Thank you for your participation today.

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Pima Medical Institute

June 18, 2003

*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 the investigators?

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Age: 23

Ethnic background: Caucasian White/Cauc.

Gender: Male

Female

Thank you for your participation today.

Please contact Jeff Long at 303-436-7906 or Jeff.Long@dhha.org if you have any other questions.

Or go to [www.denverhealth.org](http://www.denverhealth.org) and click on "Physician Research"

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**COMIRB # 03-229**

Pima Medical Institute  
June 18, 2003

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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 the investigators?

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Age: 47

Ethnic background: white

Gender: Male  Female

Thank you for your participation today.  
Please contact Jeff Long at 303-436-7906 or [Jeff.Long@dhha.org](mailto:Jeff.Long@dhha.org)  
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Or go to [www.denverhealth.org](http://www.denverhealth.org) and click on "Physician Research"

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**FEEDBACK FORM FOR PARTICIPANTS**

**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

Pima Medical Institute

June 18, 2003

*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 the investigators?

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Age: 55

Ethnic background: Caucasian

Gender: Male  Female

Thank you for your participation today.

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if you have any other questions.

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**FEEDBACK FORM FOR PARTICIPANTS**

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**COMIRB # 03-229**

Pima Medical Institute

June 18, 2003

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Yes      No

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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 the investigators?

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Age: 27      Ethnic background: \_\_\_\_\_

Gender: Male \_\_\_\_\_ Female

Thank you for your participation today.

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June 18, 2003

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Yes       No

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Yes       No

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Yes       No

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

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Age: 32      Ethnic background: Black

Gender: Male  Female

Thank you for your participation today.  
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**COMIRB # 03-229**

Pima Medical Institute

June 18, 2003

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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 the investigators?

This is a great study. I hope to see  
this study progress ASAP. It could save  
lives.

Age: 43

Ethnic background: white / Caucasian

Gender: Male  Female

Thank you for your participation today.

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June 18, 2003

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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 the investigators?

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Age: 26

Ethnic background: Caucasian

Gender: Male \_\_\_\_\_ Female

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June 18, 2003

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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 the investigators?

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Age: 32

Ethnic background: Caucasian

Gender: Male  Female

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(<http://www.denverhealth.org/TraumaCenter/Polyheme.aspx>)

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**COMIRB # 03-229**

Pima Medical Institute

June 18, 2003

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Yes      No

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Yes      No

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Yes      No

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

Seems like a great new product that  
will help save many lives.  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Age: 24      Ethnic background: Polynesian

Gender: Male \_\_\_\_\_ Female X

Thank you for your participation today.

Please contact Jeff Long at 303-436-7906 or Jeff.Long@dhha.org  
if you have any other questions.

Or go to [www.denverhealth.org](http://www.denverhealth.org) and click on "Physician Research"

(<http://www.denverhealth.org/TraumaCenter/Polyheme.aspx>)

**FEEDBACK FORM FOR PARTICIPANTS**  
**RTBSE-11-1 - PolyHeme®**  
**COMIRB # 03-229**

Pima Medical Institute  
June 18, 2003

*Please circle your answers*

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  D    
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
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\_\_\_\_\_

Age: 43      Ethnic background: Caucasian

Gender: Male \_\_\_\_\_ Female X

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Yes       No

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

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Age: 46      Ethnic background: white

Gender: Male       Female

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**RTBSE-11-1 - PolyHeme®**

**COMIRB # 03-229**

Pima Medical Institute

June 18, 2003

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Yes       No

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

I think Polyheme will be a great product, once approved I believe it to be a great help. To use the idea of military etc.  
Good Luck!

Age: 28

Ethnic background: White

Gender: Male  Female

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June 18, 2003

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Age: 24      Ethnic background: White

Gender: Male       Female

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**RTBSE-11-1 - PolyHeme®**

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June 18, 2003

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Age: 19

Ethnic background: Asian

Gender: Male  Female

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Yes      No

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

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Age: 19

Ethnic background: Cambodian

Gender: Male \_\_\_\_\_ Female

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*(<http://www.denverhealth.org/TraumaCenter/Polyheme.aspx>)*



**PolyHeme®**  
 Civilian Ambulance Trial  
 Community Consultation

**Jeffrey S. Long, RRT**  
 Senior Respiratory Therapist  
 Clinical Trials Coordinator  
 Denver Health Medical Center  
[www.denverhealth.org](http://www.denverhealth.org)



**Denver Health  
 PolyHeme Research Team**

- Jeffrey Johnson, M.D., Co-Investigator
- Jim Haenel, R.R.T., Surgical Critical Care Specialist
- Jeffrey Long, R.R.T., Clinical Trials Coordinator
- Chris Colwell, M.D., Medical Director Paramedic Division
- Craig Gravitz, EMT-P, RN, BSN, Chief Paramedic
- Jim Manson, NREMT-P Clinical Coord., Paramedic School
- Dee Martinez, Director, Marketing Communications

**Principal Investigator**

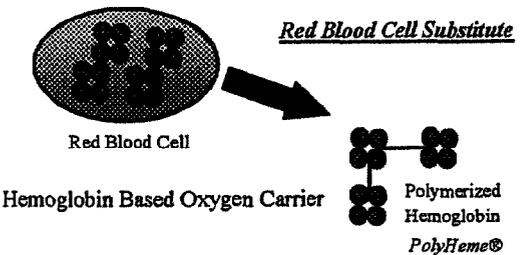


Ernest E. (Gene) Moore, M.D.,  
 Principal Investigator  
 Chief of Surgery and Trauma Services  
 Denver Health Medical Center

**Study Purpose**

*To evaluate the life saving potential of a blood substitute ... when given to severely injured patients who have suffered major blood loss ... starting at the scene of injury.*

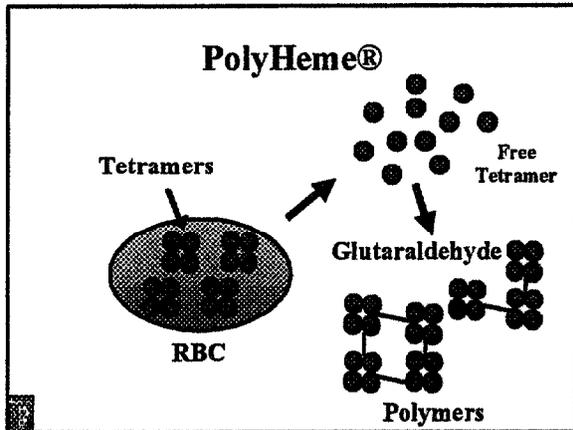
**What is a "Blood Substitute"**



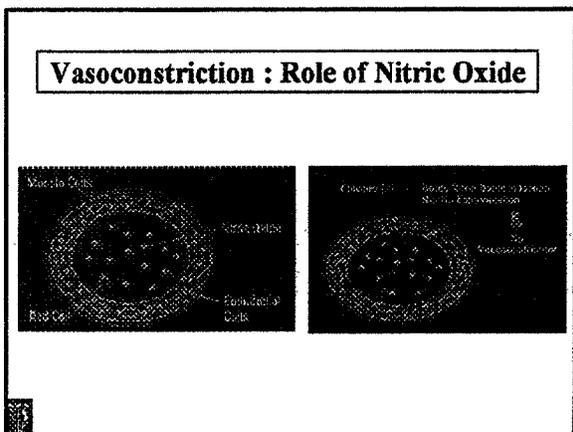
**Primary Function = Transport Oxygen**

**Beneficial Properties of a Red Cell Substitute**

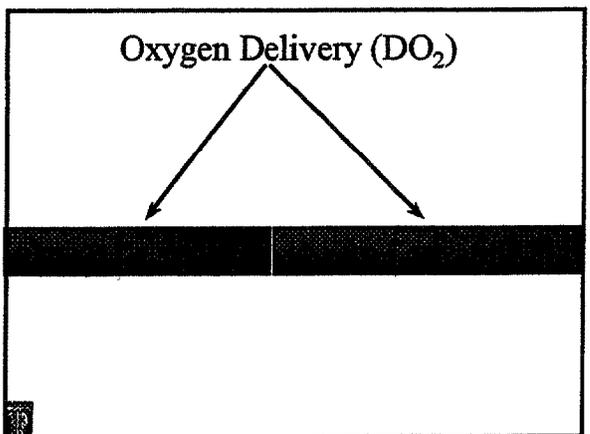
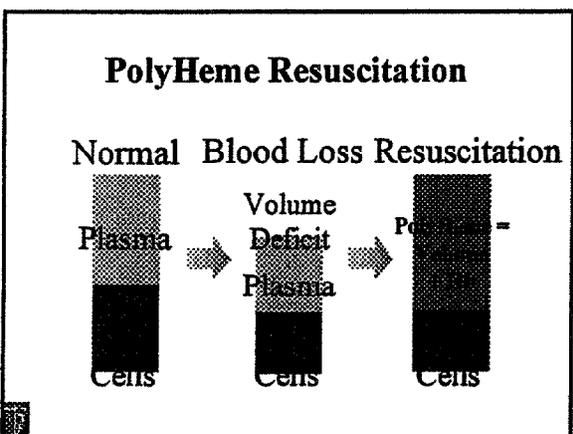
- Should provide simultaneous volume expansion and O<sub>2</sub> carrying capacity
- Should be universally compatible
- Immediately available
- Free of vasoactive properties
- Free of disease transmission
- Capable of long term storage



- ### Side Effects of Tetrameric Hgb
- Hypertension (Vasoconstriction)
  - Pulmonary Hypertension
  - Renal insufficiency
  - Gastrointestinal distress



- ### Consequences of Acute Blood Loss
- Decreased Blood Volume
  - Decreased Cardiac Output
  - Decreased Oxygen Carrying Capacity
- *Hemorrhagic Shock*



## Oxygen Delivery (DO<sub>2</sub>)

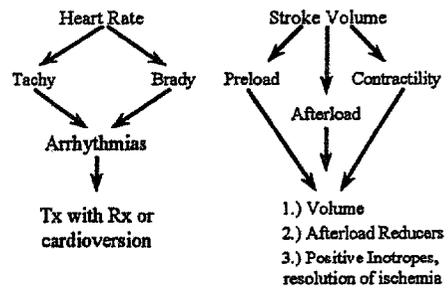
### PolyHeme

- Binds oxygen
- Carries Oxygen
- Releases Oxygen

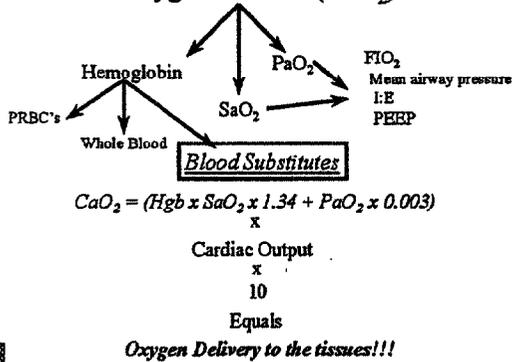
$$DO_2 = CaO_2 \times CO \times 10$$

Normal = 1250 ml/O<sub>2</sub>/min

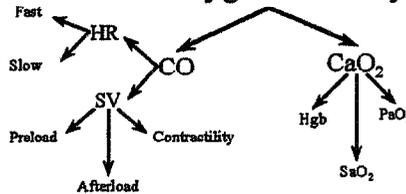
## Cardiac Output (CO)



## Oxygen Content (CaO<sub>2</sub>)



## Oxygen Delivery

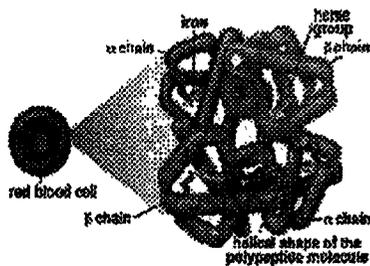


## Hemoglobin Structure

Four Subunits  
- two α  
- two β

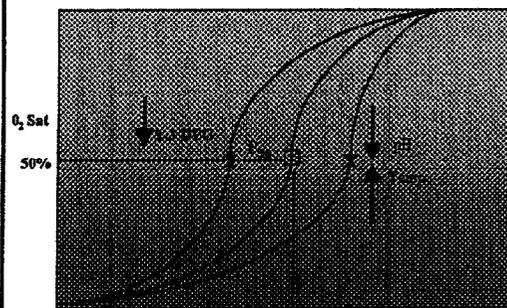
Each bound to a heme group containing iron and are capable of binding one molecule of O<sub>2</sub>

• One gram binds 1.39 ml O<sub>2</sub>



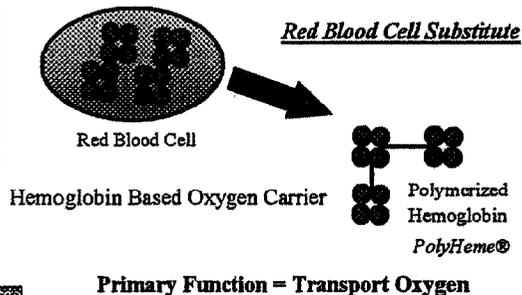
Approximately 64,500 Daltons      200-300 million per RBC

## Oxyhemoglobin Dissociation Curve



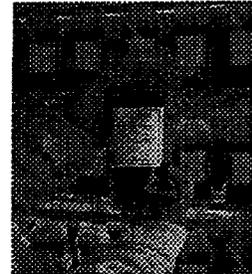
PO<sub>2</sub> (mm Hg)

## What is a "Blood Substitute"



## What is PolyHeme®?

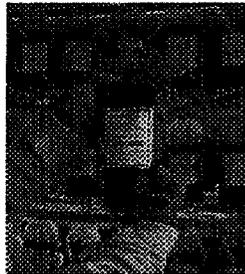
*A blood substitute ... that carries oxygen as efficiently as stored blood, using hemoglobin ... derived from outdated human blood.*



Study Sponsor: Northfield Laboratories Inc.

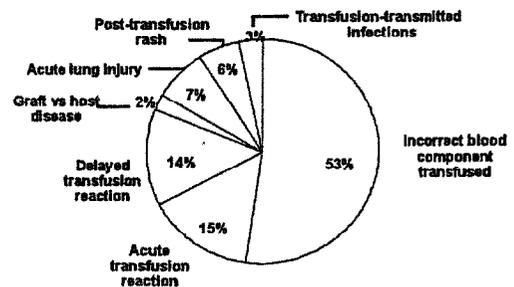
## What are the advantages of PolyHeme®?

- Compatible with all blood types; therefore it is immediately available
- Can be given using a standard I.V. in the arm



[www.northfieldlabs.com](http://www.northfieldlabs.com)

## Serious Hazards of Transfusion



Williamson LM, et al. BMJ. 1998;316:16-4.

1996 -1998  
UK and Ireland.

## Stored RBCs - ? The Risks

- Disease Transmission  
HIV, HTLV, Hep B / C
- RBC Membrane Compatibility  
Hemolytic Reactions
- Allergic Responses  
Fever, Rash, Anaphylaxis
- Immunodysfunction  
Tumor Growth, Infection, MOF
- Compromised O<sub>2</sub> Delivery  
RBC Deformability, 2 - 3 DPG



## Stored RBCs Fail to Improve Tissue O<sub>2</sub>



Doyle et al	J Appl Physiol	1990
Marik et al	JAMA	1993
Fitzgerald et al	Crit Care Med	1997
Parthasarathi et al	Am J Physiol	1999
Berezina et al	J Surg Res	2002

## Why Use PolyHeme®?

*To treat blood loss  
when stored blood is not available*

*Blood is not available  
in the ambulance*



## HBOCs : Pre-Hospital Care

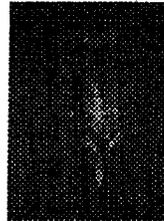


## Why a Civilian Ambulance Trial?

- The Center for Disease Control (CDC) lists trauma as the leading cause of death among Americans from 1 - 44 years of age
- More than 150,000 trauma patients die each year in the United States
- Many of these patients die because the "standard of care" cannot reverse the damaging effects of hemorrhagic shock

## What is the Standard of Care at the Scene and in the Ambulance?

Sterile Salt Water (Saline)



Limitation: Salt water does not carry oxygen

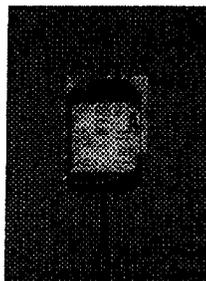
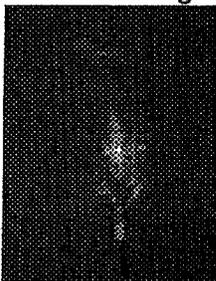
Without oxygen ... internal organs do not function properly ... and severely injured patients may die



## What is the Standard of Care in the Hospital?

Lactated Ringer's Plus

Banked Blood



## A Decade of PolyHeme® Experience

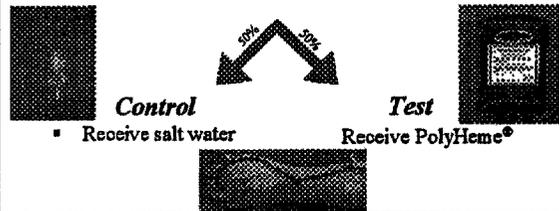
171 trauma patients at Denver Health have shown that PolyHeme®

- Carries as much oxygen as blood (1 unit of PolyHeme® = 1 unit of blood)
- Reduces need for stored blood
- Has replaced up to two times a person's entire blood volume (2 x 10 units = 20 units) with no organ damage

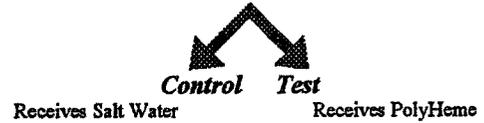
[www.denverhealth.org/TraumaCenter/Polyheme.aspx](http://www.denverhealth.org/TraumaCenter/Polyheme.aspx)

## How will this Study be Done?

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



## How will this Study be Evaluated?



**Primary Endpoint**  
Increased Survival at 30 days

**Secondary Endpoints**  
Reduce use of stored blood  
Reduce multiple organ failure  
Reduce adverse events

## How will this Study be Evaluated?



**Primary Endpoint**  
Increased Survival at 30 days

**Secondary Endpoints**  
Reduce use of stored blood  
Reduce multiple organ failure  
Reduce adverse events

## Who Would Be Included in this study?

- At least 18 years old
- Sustained severe injuries
- Lost a large amount of blood
- Are in "hemorrhagic shock"

## What is Hemorrhagic Shock?

**Hemorrhagic:** Massive blood loss

**Shock:** Dangerously low blood pressure

Internal organs don't receive enough oxygen  
May cause death

## What is the Primary Purpose of this Presentation?

Application has been made to the Colorado Multiple Institutional Review Board to approve an

*Exception from Informed Consent Requirements*  
for this clinical trial.

## Informed Consent

Traditionally required for all research studies that compare two treatments (standard vs. test)

Patients are informed of the potential risks and benefits associated with treatments

Patients choose whether to participate in the study

### Exception from Informed Consent

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

## How can that occur?

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
- Participation in the research could provide a direct benefit to the patient
- Patients are unable provide informed consent
- The research could not practicably be carried out without an exception from informed consent
- Potential risks of new treatment are reasonable
- Available treatments are not satisfactory

## Potential Benefits of PolyHeme®

*Increase the likelihood of survival because:*

- Immediately available
- Carries oxygen to vital organs
- Reduces the need for stored blood

## Potential Risks of PolyHeme®

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

## Data Safety Monitoring Board

- After 60, 120, 240, etc., patients enrolled ... an independent DSMB will completely evaluate ALL patients from both the standard and test groups for unexpected outcomes.

## Right of Refusal

*Subjects who wish to not be included in this clinical trial, may indicate their preference not to participate by means of a "Medic Alert" bracelet, or a signed note kept with their identification.*

*For Further Information or to  
offer opinion, please contact:*

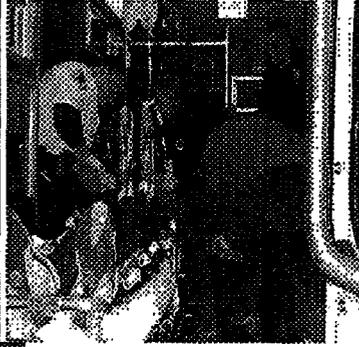
Jeffrey S. Long, R.R.T.  
Clinical Research Specialist  
Department of Surgery  
777 Bannock St.  
Mail Code 0206  
Denver, CO 80204  
303-436-7906  
Jeff.Long@dhha.org

Ernest E. Moore, M.D.  
Chief, Trauma Surgery  
Principal Investigator  
777 Bannock St  
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Or  
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Questions  
or  
Comments?



**DENVER  
HEALTH**  
Level One Care for All