

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

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

Q: Will this study include other products? A: No Q: What is the timeline, and will anyone who is injured be enrolled? A: Timeline is unknown, described inclusion/exclusion criteria. Q: Will this trial be carried out in other locations? A: Yes Q: Was this reviewed by the ethics panel at the Hospital? A: No, it was reviewed by COMIRB, we report to them (COMIRB) and they decide if we can proceed. It's very important that we reach constituents.

Comments: Council Member Gallagher asked if we needed a formal ruling from the council. Dr. Moore replied that we did not, but would appreciate their endorsement (based on implied positive response). Council Member Gallagher said he would report to group. He offered that we will likely reach many people via broadcast (live and repeat) on Channel 8 – Encouraged via channel 8 to contact us to organize meetings.

Meeting Date and Time: Tuesday, June 24, 9:00 a.m.

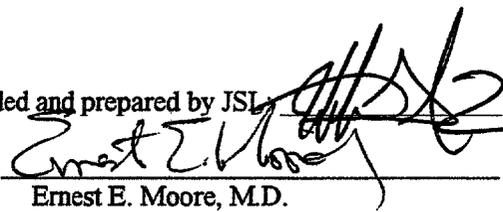
Group: Denver City Council Human Services, Health and Environment Committee

Meeting Location: Denver City and County Building,

Duration of meeting: Approximately 40 minutes

Investigator assessment: Positive

Minutes recorded and prepared by JSL

P.I. Signature: 

Ernest E. Moore, M.D.

**No surveys were returned**

Sign In Sheet

Study RTBSE-11-1 - PolyHeme

COMIRB# 03-229

Denver City Council

24, June 2003

No.	Name	Organization / Interest
1	Dennis Gallagher	Denver City Council / dgallagh@rcis.edu
2	A. Balloway	CEL Associates, Inc. / political consulting
3	Tyula Poirier	none / politics-medical /
4	Shelley Smith	City Council
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**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:

This presentation drew only 6 attendees, however extensive discussion followed. In summary one attendee voiced his concern about something he'd read (a Securities and Exchange Commission application) filed by the study sponsor, and how they'd profit if the product were to be approved. He was concerned that trauma victims would be enrolled for this study, but then the product would be marketed for elective surgery. This led us to believe that he had confused PolyHeme with a different blood substitute (Hemopure) that is also in clinical trials. Additionally, we explained that although the company would eventually make money if the product were to be approved (and explained that frankly that's part of why the company is in business) we would not benefit financially. We described that we are doing the trial because we think it has the potential to help patients. This community member also raised the point that he was concerned about the possibility that this trial would include patients without the ability to pay for medical services, but then if the product were to be approved it would no longer be available for these same "underprivileged" patients. Specifically, that there is little indication that this product will be available to the general public. Is DHMC prepared to make this available to everyone if approved? The citizen was told that at Denver Health, everyone is entitled to, and receives the same treatment. We gave an example, that two recently approved drugs (Xigris and Recombinant Factor VIIa) have both been used multiple times, and that they cost thousands of dollars per dose – irregardless of the patients financial or social status. Additionally, Dr. Colwell (co-investigator) remarked that as the paramedic Medical Director, he is encouraged that if available, he'll have this on every ambulance, available to any patient that needs it. Jim Haenel, who is the surgical critical care specialist, offered to allow this person to spend time with him, on the job, so that he would be assured that DHMC cares for all patients equally. Additionally this same person thought it was inappropriate for the product to be called by its "trade" name and not it's "scientific" name.

A different community member referred to a previous blood substitute trial (Baxter – diasprin crosslinked product) in which there was an increased mortality rate in the experimental group as compared to the control group and emphasized that, that trial was stopped because of the mortality. She was told that while that was true, it was a completely different product, and was not administered as an oxygen carrier. Additionally, the trial was repeated in Europe and the mortality rate was essentially the same in each group concluding that the product was in fact safe, and not responsible for the deaths in the U.S. trial. We emphasized the requisite utilization of the data safety monitoring board and the fact that we've used this product in multiple patients and have not had any serious events or deaths attributable to the product. Additionally, we're required not only morally but legally to report any serious events to the IRB and FDA immediately.

Additionally, there were multiple specific questions asked:

Q: What about patients with objection to blood products? A: It's been our experience that they will accept Polyheme, in fact the study sponsor receives numerous calls for the product specifically for Jehovah's Witnesses. Q: What will product cost? A: Unknown but likely comparable to blood. Q: Will temperature fluctuations on the ambulance effect safety/stability? Q: No. Product will be stored in a temperature-controlled environment (cooler with ice packs) plus the product has an extended shelf life even in extreme temperatures. Q: Is the extended shelf life secondary to chemicals? A: No. Blood breaks down at the cellular (membrane) level. Hemoglobin is much more durable. This product is pure hemoglobin - no cells. Q: How do you know if an adverse event is related to PolyHeme? A: On a case by case basis, must be addressed medically and on our experience. Again, that's why we'll have DSMB. Q: Will other study sites run concurrent with DHMC? A: Yes Q: Does PolyHeme denature into Dimers? A: No Q: Is oxygen carrying capacity better than RBC's A: PolyHeme carries oxygen as well as RBC's and may actually release oxygen better than RBC's.

Feedback forms were distributed, however none were returned. At least one participant indicated he'd send it via Mail, but it has not yet been received.

Meeting Date and Time: Thursday, June 24, 7:00 pm

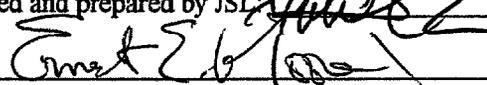
Group: Open forum - Denver Community

Meeting Location: Rita Bass Trauma and EMS Education Institute

Duration of meeting: Approximately 90 minutes

Investigator assessment: Initially hostile - eventually 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

Open Forum - Rita Bass

24, June 2003 - 7:00 pm

No.	Name	Organization / Interest
1	Sten Allen	Concerned citizen
2	NICOLE HOUSTON	THE NICOLE HOUSTON SHOW
3	Herman Polica	PUBLIC
4	Maurantha Everett	Public Interest
5	Tamara Masuno	Surgery DHMC
6	John Maisouave	DHPD
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**Community Open Forum concerning PolyHeme – a blood substitute**

JUNE 24th meeting at 7 P.M.

Rita Bass Trauma and EMS Education Institute  
190 West 6th Avenue (southeast corner of 6th and Bannock)  
Channel 7 News will be in attendance.

What do you know about the PolyHeme blood substitute study that is up for approval? The study subjects are patients involved in trauma that are transported to Denver Health. A large number of this population is underserved, uninsured, Under Represented Minorities and homeless individuals. If you live or work in Denver, you should know about this study.

Please read the links below to learn more about the study.

[www.denvernursingstar.com/newsletter](http://www.denvernursingstar.com/newsletter)

<http://www.northfieldlabs.com/releases/052203.htm>

[http://www.noonanrusso.com/news/view\\_newsitem.aspx?ItemID=402](http://www.noonanrusso.com/news/view_newsitem.aspx?ItemID=402)

<http://www.african-spectrum.com/2002/09/health2.html>

Here is an update on the study and its progress. The blood substitute has been used for patients that have been in the Emergency Room and were able to give consent as well as patients that have had scheduled surgery. Now it is ready to be used in emergency medicine with trauma patients that will not be able to give informed consent. Thus, an informed consent waiver has been requested.

If this study is approved, patients will be enrolled in the study and will receive the PolyHeme blood substitute without their consent. A similar study was conducted in 1999 but was abruptly stopped when 46% of the patients that had received the blood substitute died. What about patients that have cultural or religious objections to blood or blood products? What are the side effects? What are the known risks? What if the patient has a blood or heart condition that may react negatively to this substitute? These are all questions that deserve an answer. Also, keep in mind that if a waiver of informed consent is approved, the patients medical record will be open for review by members of the research team and will not be fully covered by the privacy laws which include HIPPA. This is concern!

The study has to receive Community approval before it will be approved by the Colorado Multiple Institutional Review Board (COMIRB). A large number of people remain unaware of the study and how it may directly affect them.

If you are unable to attend any of the community meetings but would like to share your opinion of support or opposition to this study, please send a letter to:

Ken Easterday  
Chair of Panel A  
Colorado Multiple Institutional Review Board (COMIRB)  
University of Colorado Health Sciences Center  
P.O. Box 6508  
Mailstop F 495  
Aurora, CO 80045-0508