

July 14, 2003

Colorado Multiple Institutional Review Board  
13001 E. 17<sup>th</sup> Place  
Building 500, Room N3214  
Aurora, CO 80010-7238

RE: COMIRB Protocol Number 03-229

A PHASE III, RANDOMIZED, CONTROLLED, OPEN-LABEL, MULTI-CENTER, PARALLEL GROUP STUDY USING PROVISIONS FOR EXCEPTION FROM INFORMED CONSENT REQUIREMENTS DESIGNED TO EVALUATE THE SAFETY AND EFFICACY OF POLY SFH-P INJECTION [POLYMERIZED HUMAN HEMOGLOBIN (PYRIDOXYLATED), POLYHEME] WHEN USED TO TREAT PATIENTS IN HEMORRHAGIC SHOCK FOLLOWING TRAUMATIC INJURIES BEGINNING IN THE PREHOSPITAL SETTING

I'm writing to summarize my efforts to secure community consultation meetings for the above-mentioned clinical trial.

As noted in previous correspondence to the IRB sent by the investigators, there has been a large amount of information already disseminated to the community in the form of public notices and display ads in numerous publications, community meetings, and public forums as well as news coverage. Additionally as part of said correspondence, letters have been submitted to each member of the Denver Community Health Services Committee, requesting recommendations for additional groups with whom we might schedule meetings. At the time of this writing, we have not received any response to those letters. In the following paragraphs, I'll discuss efforts to schedule additional community meetings, which to this point have been largely unsuccessful, primarily due to expressed disinterest or inability to achieve a response.

During the months of April and May 2003, multiple organizations were contacted in an effort to achieve a large audience for our initial community consultation and press conference which occurred on May 19, and to coordinate community consultation meetings. These organizations included:

The Health Sciences Center Community (via E-mail)

Associated Press  
CNN  
Crain Communications  
NBC News  
New York Times  
Reuters  
USA Today

Colorado Public Radio  
KOA Radio  
KHOW Radio  
Radio Unica

WB-TV, Channel 2  
KMGH-TV, Channel 7  
KUSA-TV, Channel 9  
Fox 31-TV, Channel 31  
Fox News (national)  
Univision, Channel 50 (Hispanic)

The Denver Business Journal  
The Denver Daily News  
The Denver Post  
Rocky Mountain News  
5280 Magazine

Boulder Daily Camera  
Metro North News  
Outfront Colorado  
Neighborhood Life  
North Denver News  
North Denver Tribune  
Arvada Sentinel  
Jefferson County Sentinel  
Golden Transcript  
Cherry Creek Times  
The Villager  
Urban Spectrum  
Washington Park Profile  
Ella Magazine  
La Voz  
El Seminario  
African Voice  
In the Black  
Intermountain Jewish News  
Women of Colorado  
Denver Nursing Star  
Denver Catholic Register  
Colorado Chinese News  
HOLA Colorado  
Denver Rocky Mountain Jiho  
Diversity Inc.  
Denver Herald Dispatch

In addition during the same time period, I attempted to schedule educational / informational meetings with; The Denver Black Church Initiative, The Hispanic Chamber, KUVU, Kappa Alpha Psi (local chapter), and the Peter Boyles Show on KHOW (630 AM), none of which were interested in our presentation. I've attempted contact with some of these groups recently, but have not been able to schedule additional meetings.

We did schedule with the Five Points Neighborhood Association who cancelled our presentation twice. While we haven't attempted to schedule specifically with LARASA, Rosario C. de Baca has been in attendance at two of our presentations and has responded positively at each, but has yet to schedule us to present to a LARASA group.

The coverage we received in the media from the May 19 presentation was tremendous. Not only did the story run multiple times on all of the local news channels and in local print media, but it was also picked up statewide and even nationally airing in more than 45 markets in the first month alone.

Since the first meeting on May 19, we've completed nine community consultation meetings, and Dr. Moore, Jim Haenel and Jeff Long were interviewed on The Nicole Houston Show (DCTV) on July 9, which according to Ms. Houston reaches a widely diverse segment of the population. Ms. Houston has been very supportive, and neither she, nor we have received any correspondence from community members as a result of that interview. Additionally, in association with Dean Brown (chair of the Denver Community Health Services Committee), we have tentatively scheduled a meeting with the Far Northeast Neighborhood Association in Montbello on August 14. Lastly, our presentation to the Denver City Council was aired repeatedly on Channel 8. Tapes of both of the aforementioned television shows are available.

If you have further questions or require additional information, please don't hesitate to contact me, or study coordinator Jeff Long.

Sincerely,

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