

**Documentation of
Community
consultation and
Public Disclosure**

October 18, 2005

Polyheme® Clinical Trial Community Plan Summary
Jon Michael Moore Trauma Center
West Virginia University Hospitals
Morgantown, West Virginia

In order to meet the requirements for the Exception from Informed Consent when conducting emergency research permitted under the regulations (Title 21, Code of Federal Regulation [21 CFR] Section 50.24) the following will describe our community consultation plan. The goal of this consultation was to gain knowledge about the communities concerns, about this research, activity. Also, the plan provided an opportunity for local communities a platform to solicit opinions and provide information to the area where study subjects will be drawn.

Key points emphasized in the campaign included:

- (1) WVU needs their help in completing a research project that can save lives after severe traumatic accidents.
- (2) This research involves giving some severely injured patients in need of transfusions a blood substitute for a limited period of time.
- (3) Blood substitute therapy has been tested extensively for effectiveness & safety.
- (4) That such research can only be done in emergency situations.
- (5) That the potential benefit is that injured people who today face the possibility of dying because of lack of blood, could receive a blood substitute that carries needed oxygen into their system.
- (6) That WVU considers the risk in this research to be minimal, but the potential to be far reaching.
- (7) Study participants will be enrolled under CFR, 21, 50.24- Exception form Informed Consent. As soon as possible informed consent will be obtained from the patient or a legally authorized representative.
- (8) Individual in the community that wish not to participate in this project may decline by wearing the special blue bracelet (I decline the Northfield Polyheme® Study), which will be made available on request.

TARGET AREA:

The project will take place in Harrison, Marion and Monongahela counties of West Virginia. The goal for the community consultation aspect of this project is to conduct a public informational campaign for the surrounding counties in the service area of the Trauma Center.

MEDIA

WVU Health Sciences Communications has provided information to the news media and arranged interviews for Lawrence Roberts, MD, FACS. Dr. Roberts talked with local

newspaper editors and broadcast news managers to explain the study and to provide an avenue for informing the community.

Press Release – Week of May 16, with the help of the WVU Communications office a public information campaign began. The WVU IRB reviewed and approved all materials.

- Newspapers: (Daily) Morgantown Dominion Post, Fairmont Times West-Virginian, Clarksburg Exponent, and (Weekly) Morgantown Times, Bridgeport News, Shinnston News and Harrison County Journal
- Television: Stations WBOY in Clarksburg, and WDTV in Clarksburg.
- Radio stations: WVHF-FM in Clarksburg, WOBG-AM in Clarksburg, WHAR-AM in Clarksburg, WVUC-FM in Fairmont, WMMN-AM in Fairmont, WAJR-AM in Morgantown, WCLG-AM in Morgantown, and West Virginia Public Radio.

Editor contact:

During the week of May 23, Bill Case from Communications made personal contact with the key editors of the three daily newspapers listed below and discussed allowing Dr. Roberts to seek newspaper assistance in informing the community. The approach in each community varied depending in part upon response from the editor(s) – it included op-ed column written by Dr. Roberts; a newspaper editorial based on information we supplied, or a community meetings and letters to public officials.

Contacts: Geri Ferrara, Editor, Dominion Post

Hope Stephan, managing editor or Bill Byrd, Times-West Virginian
John Miller, managing editor, Exponent-Telegram

Broadcast programming:

July 15, 2005, Dr. Roberts appeared as a guest on the half-hour health talk show carried by WAJR radio in Morgantown, which is sponsored by WVU. WVU HSC communications continues to encourage other reporters who regularly contact us for story ideas do pieces on Polyheme.

COMMUNITY ORGANIZATION:

Informational Letters:

The WVU HSC Communication Department provided a list of 212 community-based organizations, which a total of 120 of these organizations were felt to have a possible relationship with the Trauma Center. In addition, letters were sent to City Council member of the three largest cities (Morgantown, Fairmont and Clarksburg) and County commissioners in Monongalia, Marion, and Harrison counties to provide information and request input on this research project. The request for follow-up is detailed below.

Appearances:

WVUH Trauma Services arranged for Dr. Roberts to attend scheduled meetings to explain the research project and answered questions or concerns of the local community. The requested meetings are as follows:

June 29, 2005--Fairmont (Kiwanis and the Fairmont Clinic)

July 13, 2005—Fairmont (Knights of Columbus)

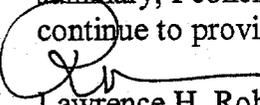
August 30, 2005—Morgantown city Council

Furthermore, additional community forums will continue to be scheduled by the project staff when contacted by interested individuals or group. On October 25, 2005 Dr. Roberts is scheduled to present the information on the research project to a community organization (Lion Club, American Legion and other interested community members) in Mannington, West Virginia.

SUMMARY:

During a WVU IRB meeting in July 13, 2005 I gave a verbal report of the summary to date and answered IRB member questions concerns about the community consultation and implementation plan. The synopsis of the report follows: Analysis of the returned survey indicated that respondents were in agreement that this research was important and needed to be carried out. Also, all respondents indicated that they would participate and agreed that they would want their family members to participate. Furthermore, at none of the meetings were there any concerns about exception from informed consent in the context of this study. All agreed that consent should be obtained when possible (by the patients in the ED if stable or by a family member as soon as they could be approached).

In addition, to date there has many positive replies and no negative comments. In summary, I conclude that we have met the requirements of the process and we will continue to provide requested updated information to the IRB.


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