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WestVirginiaUniversityHospitals
JON MICHAEL MOORE TRAUMA CENTER

Review Board for the
of Human Research Subjects
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APPROVED
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PUBLIC NOTICE

West Virginia University Hospitals' Jon Michael Moore Trauma Center is set to embark on a research study in severely injured people.

The study will evaluate the possible benefit of using a blood substitute fluid instead of saltwater.

Trauma is the leading cause of death among Americans under the age of 45. In severe trauma with shock, one out of five patients currently die.

Blood is not available in ambulances. When paramedics need to replace blood lost in an injured patient, they currently use saltwater (also called saline). Saltwater is safe for all patients, but unlike blood, it does not carry oxygen.

However, PolyHeme®, an oxygen-carrying blood substitute, can be available in ambulances, and it is the substance whose usefulness we will study.

In a nationwide study currently involving 30 trauma centers, PolyHeme® will be compared to standard saltwater for replacement of blood loss in critically injured patients who are in shock. This study is aimed at evaluating whether PolyHeme® changes patient survival as compared to saltwater.

The study begins in the field at the accident site, where paramedics will provide Polyheme to selected patients. Throughout the three-month study period, all patients will be carefully evaluated, both those who received Polyheme in the emergency situation and those given saltwater.

Because a critically injured patient in shock is unable to give informed consent to a medical treatment, federal regulations (Exception to Informed Consent 21 CFR 50.24) allow consent to be given by the patient or a family member afterwards. These regulations require that we consult with the communities in which research will be conducted, and disclose the research plan, the risks and expected benefits.

This study will be conducted in Monongalia, Harrison and Marion counties. It will involve severely injured patients who are in shock and will be transported to the Jon Michael Moore Trauma Center of West Virginia University Hospitals, Morgantown.

PolyHeme® is manufactured by Northfield Laboratories Inc., of Evanston, Illinois. Website: http://www.northfieldlabs.com/PolyHeme.html

YOU CAN OPT OUT

People who do not wish to be candidates for this study, in the event that they are seriously injured, may choose in advance to opt out.

If you do not wish to be a potential participant in this study, please obtain and wear an "I decline the Northfield PolyHeme® Study" bracelet by calling (304) 598-4659. Or you can pick up a bracelet at these locations: Morgantown Public Library System (all locations), Marion County Public Library, Marion County Rescue Squad, Bridgeport Public Library, or the Clarksburg-Harrison Public Library.

For additional information, questions, or concerns, please contact Bill Manley, RN, at (304) 598-4659 or by E-mail: manleyw@rcbhsc.wvu.edu