Type O Whole blood and assessment of AGE during prehospital Resuscitation (TOWAR) trial

Consent for Continuing Participation

NCT 04684719

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University of Pittsburgh

CONSENT TO CONTINUE PARTICIPATING IN RESEARCH

PATIENT/LEGALLY AUTHORIZED REPRESENTATIVE CONSENT FOR CONTINUING PARTICIPATION IN RESEARCH

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STUDY TITLE: LITES TASK ORDER 7
Type O Whole blood and assessment of AGE during prehospital Resuscitation (TOWAR) trial.

SOURCES OF SUPPORT: This study is being funded by the Department of Defense (DoD)

The word "YOU" throughout this document refers to the person injured. In cases where the injured person is unable to read and understand this form for themselves, this form is being provided to the legally authorized representatives acting on the injured person's behalf.

INTRODUCTION
You are being asked to continue to participate in a research study. Before making this decision, you need to understand the risks and benefits of this study. This is known as informed consent. This consent form provides information about the research study that has been explained to you. Once you understand the study and what is required to participate, you will be asked to sign this form if you would like to continue in the study. Your decision to continue to take part in this study is voluntary. This means you are free to choose if you will continue in the study. This research study will enroll 1,020 patients across the country.

PURPOSE OF THE STUDY
This study is being done to see if giving whole blood transfusion early in the course of treatment would help severely injured patients that lose a lot of blood (hemorrhagic shock) survive their injuries. Whole blood may have been given to you even if you were not part of this research study, but not until you arrived at the hospital. There is information that suggests that severely injured people who are given whole blood before coming to the hospital need fewer blood transfusions and have fewer complications while in the hospital. Whole blood is normally stored for up to 35 days. We are also trying to see if giving younger whole blood (less than 14 days old) or older whole blood (older than 14 days old) will change some of your labs such as clotting times and markers of inflammation.

In order to find out these answers, some EMS services/agencies will be carrying whole blood. We are having some EMS helicopters and ambulances carry whole blood and others not carry whole blood to compare people who got whole blood to people who did not. You were enrolled in this study because you had a traumatic injury that resulted in a lot of blood loss. Depending on what EMS service/agency transported you, you may or may not have been given whole blood through your vein by the paramedics who treated you for your injury. The alternative to receiving whole blood as part of this study is standard care, which could include whole blood, blood components, or other fluids. All other medical care provided to you for your injury was standard medical care for your condition. The whole blood used for this study is Type O, which may not match your blood type. However, giving Type O blood to people in emergency situations is standard care. We use a particular kind of Type O blood for the study that has a low risk for any reactions. In addition, we also have obtained data about the incident from the EMS service/agency that cared for you at the scene and your hospital records. Due to the nature of the emergency, it was impossible to obtain your written consent prior to enrolling you in this study. You are being provided with this consent in order to provide you with information so that you can determine if you would like to continue in this study.

We would like to continue to collect information from your medical records to follow up on your health during your hospital stay and the treatment that you receive while in the hospital. The reason for getting this additional information is to better understand how the method used for reviving you from your severe injuries impacted your recovery. This information may include time spent with EMS and in the hospital and the type of care you got in the ambulance and hospital, information such as date of birth, age, gender, test results and any illnesses or set-backs you experience while you are in the hospital. We will collect information about how each of your body systems is doing by recording lab values and procedures that are done as part of your care.

We would also like to collect a small amount (less than 2 tablespoons) of blood close to when you arrive at the hospital and again around 24 hours to look at how your blood is clotting. Depending on the time of this consent, you may or may not have had all of the blood collections.
We may contact you at the phone number you have provided after 30 days to check on your status. If you are discharged to another facility, we may contact that facility for an update on your condition or search public records for your status.

Your data may be shared with other scientists and researchers outside of this hospital facility who are also studying trauma injuries. Your name and identifying information will be removed from the data and will be replaced with a unique code before they are sent to anyone.

POTENTIAL RISKS AND DISCOMFORTS
There are risks as part of being in this study. Please note that you have already been exposed to some of these risks, but due to the seriousness of your injury these procedures would have been performed on you anyway, as part of your medical care. You have already received either whole blood, blood components like red blood cells, or special fluids like saline.

You may have blood drawn by a needle (venipuncture) soon after you arrive and again close to 24 hours. Risks of venipuncture include pain, bleeding at the site, dizziness or fainting and, rarely, infection.

If you received whole blood and had the whole blood infused as part of the study, the following infusion risks applied to you:

Rare (<1% chance): Fever or dangerously low body temperature; respiratory distress (shortness of breath) or lung injury; kidney damage as a result of metabolic changes; systemic infection; exposure to blood borne micro-organisms (bacteria and parasites) that could result in an infection; allergic or other serious reactions in the blood cells with possible side effects on the immune system, which may decrease the body's ability to fight infection; shock; death. Women with Rh-negative blood types who are still able to have children that receive Type O positive blood are at risk of their future unborn babies having a condition called hemolytic disease of the fetus and newborn (HDFN). HDFN can cause the unborn baby to have low blood counts, more fluid buildup than normal, and in very rare instances, death.

Extremely rare (one in a million or less): Exposure to blood borne viruses such as hepatitis (an inflammatory disease affecting the liver) and Human Immunodeficiency Virus (HIV, the virus that causes AIDS).

The only risk of continuing participation in this study is a risk of confidentiality, which is discussed below.

ANTICIPATED BENEFITS TO SUBJECTS
We are conducting this study because we anticipate that the benefits of getting whole blood may reduce bleeding in some patients, and possibly reduce overall blood transfusion requirements during the first day after your injury. If you received whole blood before arriving at the hospital you may have had less bleeding or needed fewer transfusions the first day after your injury. Ultimately your participation may help us better understand and improve prehospital treatment of trauma injuries in the future.

ALTERNATIVES TO PARTICIPATION
The alternative is to receive standard medical care without collection of your medical information or blood for research.

PAYMENT FOR PARTICIPATION
You will not be paid for participation in this study.

COSTS OF PARTICIPATION
There are no additional costs to you for continuing to participate in this study. Clinical care provided will be charged in the usual manner as part of your standard medical care (care you would receive even if you were not participating in this research study).

MEDICAL CARE FOR RESEARCH RELATED INJURY
UPMC and their associates who provide services at UPMC recognize the importance of your voluntary participation in their research studies. These individuals and their staff will make reasonable efforts to minimize, control, and treat any injuries that may arise because of this research. If you believe that you are injured because of the research procedure being performed, please immediately contact the principal investigator listed on the first page of this form.

Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. It is possible that the hospital may bill your insurance provider for the costs of this emergency treatment but none of these costs will be charged directly

to you. If your research related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated above. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form.

CONFIDENTIALITY

We make every effort to keep the information about you confidential. You have been assigned a study code number. This code number, and not your name, is used on all of the data we collect. The data collected may be shared with other doctors and research scientists outside of the University of Pittsburgh/UPMC. A key linking you to the code number is kept in a secure location and will be available only to the investigators and their research teams. The data will be retained indefinitely and used for future studies. Data from this study, without your identity, may be reported in scientific meetings, articles and other appropriate communications. We will notify the community of the results through scientific papers, presentations at scientific meetings, and through local media.

If you sign this document, you give permission for continued access to your health information that identifies you for the research study to the following groups:

The investigators listed on the first page of this consent form and their research staff, authorized representatives of the University of Pittsburgh Office of Research Protections, the Department of Defense, and the FDA may access your research records as part of their responsibility to protect human subjects in research. This information can be requested by and provided to courts or legal authorities.

Your permission to access your health information for this study does not expire.

Authorized representatives of the University of Pittsburgh/UPMC or other affiliated health care providers may have access to your identifiable information (which may include your identifiable medical record information) for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (such as laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; (3) for internal hospital operations (i.e. quality assurance).

SUBJECT ACCESS TO RESEARCH RESULTS

In accordance with the University of Pittsburgh/UPMC Notices of Privacy Practices document that you have been provided, you are permitted access to research results contained within your medical records filed with your healthcare provider. Please note that such access may be limited to the end of the research study.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

PARTICIPATION AND WITHDRAWAL

Your continued participation in this research is voluntary. If you choose not to continue to participate, that will not affect your relationship with your providers or your right to health care or other services to which you are otherwise entitled. If you decide to continue to participate, you are free to withdraw your consent

and discontinue further participation at any time without prejudice. You can do this by contacting the Principal Investigator listed on the first page of this form.

CONSEQUENCES OF WITHDRAWAL
If you choose to withdraw your participation, we will not collect any further information from your medical record. We will stop all remaining study activities, but we will keep the data that we've already collected during your participation.

WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR
The investigator may withdraw you from continuing participation in this research if circumstances arise which warrant doing so. The investigator may make the decision and let you know it is not possible for you to continue. This decision may be made either to protect your health and safety, or because your condition did not meet the criteria needed for study inclusion.

NEW FINDINGS
During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation. If new information is provided to you, we will ask for your consent to continue participation in this study.

IDENTIFICATION OF INVESTIGATORS
In the event of a research related injury or if you experience an adverse reaction, please immediately contact the investigator listed on the first page of this form. If you have questions about the research, please feel free to contact the PI or Co-PI listed on the first page of this form.

RIGHTS OF RESEARCH SUBJECTS
You may withdraw your continuing consent at any time and discontinue further participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research subject, you may contact the Human Subjects Protection Advocate University of Pittsburgh toll-free at 1-866-212-2668.

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SIGNATURE OF RESEARCH SUBJECT
VOLUNTARY CONSENT

The study has been explained to me and all of my questions have been answered. I understand that, throughout my participation in this research study, I am encouraged to ask questions about any aspect of this research study including the use and disclosure of my identifiable medical record information. Any additional questions or concerns about any aspect of this study will be answered by the investigators listed on the first page of this form.

Any questions I might have about my rights as a research participant or the research use of my medical information will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh at 1-866-212-2668.

By signing this form, I agree to participate in this research study and provide my authorization to share my medical records with the research team. A copy of this consent form will be given to me.

Participant's Signature	Printed Name of Participant	Date	Time

SURROGATE CONSENT

_____ is unable to provide direct consent for study participation.
Participant's Name (Print)

Therefore, by signing this form, I give my consent for his/her continued participation in this research study.

Representative's Name (Print)	Relationship to Participant

Representative's Signature	Date	Time

PARENTAL PERMISSION

I understand that, as a minor (age less than 18 years), the above-named child is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my permission to enroll my child and authorize the research team's access to my child's medical records.

Signature of Parent or Guardian	Printed Name of Parent or Guardian	Date	Time

ASSENT of a Minor Participant

This research has been explained to me and I agree to participate.

Participant's Signature	Printed Name of Participant	Date	Time

CONSENTER'S CERTIFICATION

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the subject or their representative or family member and any questions about this information have been answered.

Research Staff Signature	**Research Staff Name (Print)**	**Date**	**Time**

CONSENT FOR CONTINUED RESEARCH PARTICIPATION
I am currently participating in a research study in which consent for my participation was initially obtained from my legally authorized representative as a result of my inability to provide consent at the time. I have now recovered to the point where the study doctor believes that I am able to consent to continued participation in this research study.

I have read the information in this consent form. The study has been explained to me, and all of my current questions have been answered.

I agree to continue my participation in this research study.

_____	_____	_____	_____
Participant's Signature	Printed Name of Participant	Date	Time

CONSENT FOR CONTINUED PARTICIPATION (adolescent turns 18)
I understand that I am currently participating in a research study. I further understand that I may have given assent for my participation in this research study because I was a minor at the time I was asked to be in the study. I have now turned 18 years old, and I am able to provide direct consent for continued participation in this research study.

The study has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns, or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable. By signing this form I agree to participate in this research study.

By signing below, I agree to continue my participation in this research study. A copy of this consent form will be given to me.

_____	_____	_____
Participant's Signature	Date	Time

CONSENTER′S CERTIFICATION
I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the subject and any questions about this information have been answered.

_____	_____	_____	_____
Research Staff Signature	**Research Staff Name (Print)**	**Date**	**Time**