Cold-stored Platelet Early Intervention in TBI (CriSP-TBI)

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INFORMED CONSENT AND HIPAA AUTHORIZATION FOR CONTINUING PARTICIPATION IN A RESEARCH STUDY

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STUDY TITLE: Cold Stored Platelet Early Intervention - TBI (CriSP - TBI)

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

For non-emergency, study related questions during business hours, please call: **(412) 383-8326**

This form is for use in a research study that involves participants who do not have the capacity to consent to take part in the study. If you are the legally authorized representative of the patient, you will be asked to provide your consent. In cases where the participant's representative gives consent, the participant should be informed about the study to the extent possible if the participant regains capacity to consent. During the study, if the participant regains the capacity to consent, informed consent will be obtained from the participant and the participant offered the ability to leave the study if desired.

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.

KEY INFORMATION

- You are being asked to continue to participate in a research study that is being done to see if giving cold-stored platelets early in the course of treatment is feasible and if it would help improve outcomes in patients with traumatic brain injury. Due to the nature of the emergency, it was not possible to obtain informed consent before enrolling you in this study. This consent provides you with information so you can decide if you want to continue to participate in this study.

- As a result of your injury, you received either cold stored platelets or room temperature platelets as part of usual care soon after arriving at the hospital. We also obtained data about the incident from the pre-hospital reports and your hospital records and may have collected up to two blood samples.

- We would like to continue to collect information from your medical records to follow up on your health during your hospital stay and the care that you receive while in the hospital. If you choose to continue to participate, we will collect information from your hospitalization up to thirty days. If you are discharged, we may call you after 30 days and again after 6 months to check on your status. This study also requires up to two blood samples.

- Please note that due to the seriousness of your injury, you would have received platelets anyway as part of standard medical care. Risks of receiving platelets include infection, allergic reaction, fever, and respiratory distress (shortness of breath). The risks of being enrolled in this study are related to receiving cold stored platelets early during treatment instead of standard care. We don't know if receiving cold-stored platelets increases your risk of thrombosis (clotting). We don't know if receiving cold stored platelets makes other risks better or worse. Other risks are from blood collection and a risk to confidentiality.

- We are unsure if there are benefits to one method over another. Your participation may help us better understand treatment of trauma injuries in the future.

- Since continuing to participate in this research study only involves the collection of your medical information, the only alternative is to decide not to continue in this study.

If you are interested in learning more about this study, please continue to read below.

INTRODUCTION

You are receiving this consent because you were enrolled in a research study and are being asked to continue to participate. Before you make 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, you will be asked to sign this form if you would like to continue to participate in the study. Your decision to take part in this study is voluntary. This means you are free to choose. This research study will enroll approximately 100 patients at the University of Pittsburgh.

PURPOSE OF THE STUDY

This study is being done to see if giving cold stored platelets early during treatment is feasible and if it would help improve outcomes in patients with traumatic brain injury. Room temperature platelets may have been given to you even if you were not a part of this research study as part of standard care for patients with traumatic brain injury. The cold stored platelets used in this study have been stored longer and are given earlier during treatment than room temperature platelets that are part of usual care. Although platelets stored at room temperature have been licensed for use by FDA, use of cold stored platelets stored up to 14 days is considered experimental. There is some information that suggests that people with traumatic brain injury who are given platelets soon after arriving at the hospital may have improved survival.

As a result of your injury, you have received either cold stored platelets soon after arriving at the hospital or room temperature platelets as part of usual care. A randomization process (like flipping a coin) was used to determine which you received: cold-stored or room temperature platelets.

Depending on the randomization, you may or may not have been given cold stored platelets. All other medical care provided to you for your injury was standard medical care for your condition. In addition, we

have also obtained data about the incident from the pre-hospital reports and your hospital records. Due to the nature of the emergency, it was not possible to obtain informed consent before enrolling you in this study.

This study is only done in emergencies. The Food and Drug Administration (FDA) has special rules that allow studies looking at emergency interventions to be done without consent. One of these rules is that we can only use interventions that we think could help people. Another rule is that the study team must talk to members of the community where the study will happen to get their opinions on the research.

We would like to continue to collect information from your medical records to follow up on your health during your hospital stay and the care that you receive while in the hospital. The reason for getting this information is to better understand how the temperature of platelets used to treat your injury impacted your recovery. The information may include time spent in the hospital and the type of care you got, information such as date of birth, age, gender, test results and any illnesses or setbacks you experience while you are in the hospital. If you agree to continue, 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. Your permission to access your health records for the purposes of this study does not expire.

This study also requires up to 3 tablespoons of blood to look at levels of medication and how your platelets are functioning after you receive the first dose of platelets. Following the blood collection, you may receive one more unit of platelets if needed. After that, there are no more procedures that will be performed as part of this study. You may have already had these blood collections and may have already received a second unit of platelets.

If you agree to continue to participate, we will continue to collect information from your hospitalization up to thirty days. If you are discharged before thirty days, we may call you to check on your status after 30 days and again after 6 months. If you are discharged to another facility, we may contact that facility for an update on your condition. If we are unable to get in touch with you or with the facility you were discharged to, we will check your survival status on a public access database using some of your personal identifiers such as your name, date of birth, and social security number.

Some of your samples and the information we collect about you may be shared with other scientists and researchers outside of the University of Pittsburgh. Your name and identifying information will be removed from the samples and data and will be replaced with a unique code before they are sent to anyone. We may keep identifiable information in your research chart. Any research data will not be placed in your medical records.

The procedures and study visits involved in participation are:	**Visit 1**		**Visit 2**	**Visit 3**
	Within 2 hours of Head CT scan	**Before and After Platelet Administration**	**Prior to Discharge**	**6 Months (+/-) 1 Month**
Medical record and CT scan review	✓			
Randomization of Platelet Administration	✓			
Blood Draw (3 tablespoons)		✓		
Neuropsychological & outcome assessments			✓	✓
Clinical data collection	*Ongoing for Duration of Study*			

POTENTIAL RISKS AND DISCOMFORTS

Participation in this study has exposed you to certain risks and discomforts. Please note that due to the seriousness of your injury, platelets would have been given to you anyway as part of your medical care. Although we expect that the risks of receiving cold-stored platelets are the same as receiving room temperature platelets, this is a question that the current study will examine. Risks of receiving platelets include infection, allergic reaction (mild to severe), fever, and respiratory distress (shortness of breath). Additional risks associated with platelet transfusion include bacterial contamination, platelet immune responses, and breakdown of red blood cells. The risks of being enrolled in this study are related to receiving cold stored platelets early during treatment instead of platelets as part of standard care. We don't know if receiving cold-stored platelets increases your risk of thrombosis (clotting). We don't know if receiving cold stored platelets makes other risks better or worse.

You may already have had blood drawn by a needle. Risks of having blood drawn by a needle (venipuncture) include pain, bleeding at the site, fainting, and rarely infection. Whenever possible, the blood was obtained with your clinical labs or from an indwelling catheter.

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

ANTICIPATED BENEFITS TO PARTICIPANTS

We are conducting this study to compare giving cold stored platelets early during treatment to usual care and are unsure if there are any benefits to one method over another. There is some information that suggests that patients with traumatic brain injury who are given platelets soon after arriving at the hospital may have improved survival. The risk of infection from bacterial contamination may be lower with cold stored platelets than with platelets given as part of standard care. Ultimately your participation may help us better understand treatment of trauma injuries in the future.

ALTERNATIVES TO PARTICIPATION

Since continuing in this study only involves blood collection and the collection of your medical information, no alternatives are available. The only alternative is to decide not to continue participation.

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

The use of your specimens collected for research may result in commercial applications. You will not receive money for your blood samples, nor will you receive money from any future proceeds because of this research study.

COSTS OF PARTICIPATION
There are no additional costs to you for participating 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). If you receive room temperature platelets, which are standard of care, this will be billed to your insurance company.

MEDICAL CARE FOR RESEARCH RELATED INJURY
University of Pittsburgh researchers and their associates who provide services at University of Pittsburgh Medical Center (UPMC) recognize the importance of your voluntary participation in their research studies. These individuals and their staffs will make reasonable efforts to minimize, control, and treat any injuries that may arise because of this research. If you believe that you were injured because of the research procedures being performed, please contact immediately 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 UPMC 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 below.

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 will be assigned a study code number. This code number, and not your name, is used on all the data and blood samples we collect. The samples of your blood will be labeled with a code number and will be stored. Your data and blood samples may be shared with other doctors and outside research scientists. A key linking you to the code number is kept locked in a secure location and will be available only to the investigators and their research teams. The data and samples will be retained indefinitely and used for future studies. Data from this study, without your identity, may be reported in scientific meetings, articles, or other appropriate communications. We will notify the community of the results through scientific papers, presentations at scientific meetings, and through local media.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. The Principal Investigator and other study personnel will ensure that your confidentiality will be maintained. Participant name and other identifiable information will be kept in a secure, locked, limited access area such as a password protected database.

If you sign this document, you give permission for 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. This information can be requested by and provided to courts or legal authorities.

We are requesting authorization/permission to continue to review your medical records. This research study will involve the recording of current and/or future identifiable medical information from your hospital and/or other healthcare provider (e.g., physician office) records. This authorization is valid for an indefinite period. This identifiable medical record information will be made available to members of the research team for an indefinite period. The information that will be recorded will be limited to information concerning the past, present and future medical information related to the traumatic brain injury and neurological outcome.

The following people/groups may have access to your research data and/or biospecimens: University of Pittsburgh research team and staff/UPMC staff involved in the procedures, authorized representatives of the University of Pittsburgh Office of Research Conduct and Compliance, authorized representatives of the U.S. Food and Drug Administration, ancillary labs for analysis, sponsor (DoD), FITBIR (Federal Interagency Traumatic Brain Injury Research Informatics System), and investigators in the future studying various components of health may receive deidentified data/specimens.

Your research data will be uploaded and stored at the Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System and potentially other national health research databases for broad use by approved investigators to accelerate research within the TBI field. FITBIR is a collaborative effort involving the NIH Institutes and Centers (ICs) and the US Army Medical Research and Material Command (USAMRMC) to develop a biomedical informatics system and data repository for Traumatic Brain Injury (TBI) research. The purpose of FITBIR is to share data across the entire TBI research field. Your research data stored at FITBIR will be de- identified (does not include anything that might directly identify you, such as your name). This data is important because it will help us learn about factors that lead to TBI recovery.

Authorized representatives of the Department of Defense (DoD), the funding agency for this study, may review or obtain identifiable information related to participation in this research study for the purpose of monitoring the accuracy and completeness of the research data, for performing required scientific analyses of the research data, and as part of their responsibility to protect human research volunteers. While the DoD understands the importance of maintaining the confidentiality of your identifiable research and medical information, the University of Pittsburgh and UPMC cannot guarantee the confidentiality of this information after it has been obtained by the DoD.

Text messaging: When communicating with the research study team by text message, we need to inform you that text messages are not encrypted or secure during their transmission and could be intercepted.

ACCESS TO RESEARCH RESULTS

In accordance with the 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 health care 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, this 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 may withdraw, at any time, your authorization (consent) for the use and disclosure of your identifiable medical record information for the purpose of this research study. However, if you withdraw your authorization (consent) for the use and disclosure of your identifiable medical record information, you will also be withdrawn from further participation in this research study. Any identifiable medical record information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your authorization may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your authorization (consent) you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

CONSEQUENCES OF WITHDRAWAL
This study involves randomization to receive early cold stored platelets or not, and two blood samplings (venipunctures).

If you choose to continue to participate in this study, we will obtain samples and record your data. You may later request not to have any additional data collected or samples taken.

WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR
The investigator may withdraw you from participating in this research if they feel it is best for you. The investigator will make the decision and let you know if it is not possible for you to continue. The decision may be made to protect your health and safety.

NEW FINDINGS
During 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 participating in this study again.

IDENTIFICATION OF INVESTIGATORS
. If you have any questions about the research, please feel free to contact the Principal Investigator or the Primary Coordinator listed on the first page of this document.

RIGHTS OF RESEARCH PARTICIPANTS
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.

PARTICIPANT CONSENT

COMPLETE THIS SECTION IF THE PARTICIPANT IS CONSENTING FOR THEMSELF. IF NOT, TURN TO PROXY CONSENT.

VOLUNTARY CONSENT:
The above information has been explained to me and all of my current questions have been answered. Any further questions I have about this research study will be answered by a qualified individual or by the investigator(s) listed on this consent document at the telephone number(s) given. I understand that I may always request that my questions be answered by the listed investigator. Any questions I have about my rights as a research participant will be answered by the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh 1-866-212-2668.

By signing this form, I agree to continue 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 provided to me.

_____
Participant's Name (print)

_____ _____ _____
Participant's Signature or 'Mark' **Date** **Time**

CONSENT TO PARTCIPATE IN THIS RESEARCH STUDY FOR PARTICIPANTS WHO CANNOT READ OR CANNOT WRITE HIS/HER SIGNATURE, NAME, AND DATE

The Study participant has indicated that he/she is unable to read or cannot write his/her signature, name, and date. The Informed Consent Form has been read to the participant by a member of the Study Staff, discussed with the participant by a member of the Study Staff, and the participant has been given an opportunity to ask questions of the Study Staff.

_____
Printed Name of Unbiased Witness*

_____
Signature of Unbiased Witness*

Date _____Time:_____ ☐ am ☐ pm

***Unbiased witness**: an individual who is not a study team member or a family member of the participant who will be physically present during the consent process to observe the process and sign consent forms

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CERTIFICATION OF INFORMED CONSENT:
I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise.

_____	_____
Printed Name of Person Obtaining Consent	**Role in Research Study**

_____	_____	_____
Signature of Person Obtaining Consent	**Date**	**Time**

IF PARTICIPANT SIGNED CONSENT STOP HERE

PROXY CONSENT & ASSENT
COMPLETE THIS SECTION IF THE PARTICIPANT IS UNABLE TO CONSENT FOR THEMSELF.

ASSENT FOR RESEARCH (complete if the participant is capable):
The research study has been explained to you. You have had a chance to ask questions to help you understand what will happen in this research. This research study is voluntary. If you agree to participate and later change your mind, you can tell the researchers, and the research will be stopped.

_____ _____ _____
Participant's Signature or 'Mark' **Date** **Time**

ASSENT TO PARTCIPATE IN THIS RESEARCH STUDY FOR PARTICIPANTS WHO CANNOT READ OR CANNOT WRITE HIS/HER SIGNATURE, NAME, AND DATE

The Study participant has indicated that he/she is unable to read or cannot write his/her signature, name, and date. The Informed Consent Form has been read to the participant by a member of the Study Staff, discussed with the participant by a member of the Study Staff, and the participant has been given an opportunity to ask questions of the Study Staff.

_____
Printed Name of Unbiased Witness*

_____
Signature of Unbiased Witness*

Date _____Time:_____ ☐ am ☐ pm

***Unbiased witness**: an individual who is not a study team member or a family member of the participant who will be physically present during the consent process to observe the process and sign consent forms

****
VERIFICATION OF EXPLANATION (complete if the participant was capable of assent):
I certify that I have carefully explained the purpose and nature of this research study to the above-named participant in appropriate language. He/she has had an opportunity to discuss it with me in detail. I have answered all his/her questions and he/she has provided affirmative agreement (i.e., assent) to participate in this study.

_____ _____
Printed Name of Person Obtaining Assent **Role in Research Study**

_____ _____ _____
Signature of Person obtaining assent **Date** **Time**

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VOLUNTARY CONSENT:
The above information has been explained to me and all of my current questions have been answered. Any further questions I have about this research study will be answered by a qualified individual or by the investigator(s) listed on this consent document at the telephone number(s) given. I understand that I am encouraged to ask questions about any aspect of my loved one's participation in the research study at any time, and that such future questions will be answered by the investigators associated with the Department of Neurosurgery or their research staffs. I understand that a copy of this consent form will be given to me. I understand that any questions which I have about my loved one's rights as a participant in the research study will be answered by the Human Subjects Protections Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

_____
Participant's Name (print)

Named individual is unable to provide direct consent to his/her participation in this research. Therefore, by signing this form, I give my consent for his/her participation in this research and provide my authorization to share his/her medical records with the research team.

_____ _____
Representative's Name (print) **Relationship to Participant**

_____ _____ _____
Representative's Signature **Date** **Time**

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CERTIFICATION OF INFORMED CONSENT:
I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise.

_____ _____
Printed Name of Person Obtaining Consent **Role in Research Study**

_____ _____ _____
Signature of Person Obtaining Consent **Date** **Time**

<u>INITIAL</u> CONSENT STOPS HERE

CONTINUED PARTICIPATION CONSENT

COMPLETE THIS SECTION (IF PROXY CONSENT WAS INITIALLY OBTAINED) IF THE PARTICIPANT REGAINS CAPACITY FOR CONSENT IN-PERSON.

CONTINUED PARTICIPATION CONSENT:

I have been informed that I am currently participating in a research study. I have read (or have had read to me) and understand this consent form which was previously signed by my legal representative. Any questions I have pertaining to the research have been and will continue to be answered by the investigators listed in the beginning of this consent form at the telephone numbers given. My signature below means that I freely agree to continue to participate in this research study.

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

_____	_____	_____
Participant's Signature	**Date**	**Time**

****

CERTIFICATION OF INFORMED CONSENT:

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about this study have been answered, and we will always be available to address future questions as they arise.

_____	_____
Printed Name of Person Obtaining Consent	**Role in Research Study**

_____	_____	_____
Signature of Person Obtaining Consent	**Date**	**Time**