CHIlled Platelet Study "CHIPS"

NCT: 04834414

June 10, 2024

INFORMED CONSENT DOCUMENT

TITLE: CHIlled Platelet Study (CHIPS)

PROTOCOL NO.: None
WCG IRB Protocol #20241804

SPONSOR: Dr. Philip C. Spinella

INVESTIGATOR: Name
Address
City, State Zip
Country

STUDY-RELATED PHONE NUMBER(S): Phone Number(s)

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

- If you are the parent/guardian of a child under the age of 18 who is being invited to participate in this study, the word "you" in this document refers to your child. As the parent/guardian, you will be asked to read and sign this document to give permission for your child to participate.
- If you are under the age of 18 and reading this document, the word "you" in this document refers to you. You will be asked to read and sign this document to indicate your willingness to participate.

If you are the legally authorized representative of a person who is being invited to participate in this study, the word "you" in this document refers to the person you represent. As the legally authorized representative, you will be asked to read and sign this document to give permission for the person you represent to participate in this research study.

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

KEY INFORMATION

This is a research study conducted by the study site, having to do with platelet transfusions. You should carefully consider the information in this consent document and discuss it with the research team. Be sure you understand why you might want to participate, or why you might not want to participate. You may choose to participate or not.

If you agree and sign this consent, you will be volunteering to participate in the research study. All of the information below will be explained and is listed in more detail in the consent document below. The research team must give you a copy of this signed consent document.

What is the purpose of the research?

- The purpose of this study is to compare transfusion of the investigational cold-stored platelets to standard room-temperature platelets and determine whether cold-stored platelets are equal to or better than room-temperature stored platelets at controlling bleeding. This study will also investigate the length of time platelets can be stored and remain equivalent to room temperature stored platelets.

How will this study affect me?

- You were selected because there is an expectation you may need to receive a platelet transfusion during or after your scheduled cardiac surgery due to bleeding.
- You will be in this study until you leave the hospital, and all trial-related procedures will take place during your hospital stay apart from 1 phone call if you are discharged from the hospital prior to Day 28.

What are some of the risks?

- Whether cold stored platelets have similar safety and efficacy (how well they work to stop bleeding) to room temperature stored platelets is to be determined.
- Although uncommon, some of the possible risks of platelet transfusions are:
  - Nausea
  - Chills
  - Fever
  - Drop in blood pressure
  - Shortness of breath
  - Itching and hives

What are my alternatives?

- You do not need to be in this study to receive standard of care platelet transfusions. You may discuss options with your study doctor.

What other information should I know?

- Although there is no payment for you participating, there is also no cost to you.
- If you withdraw from the study, the research team may continue to use information already collected about you while you were in the study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you may require a platelet transfusion during cardiac surgery or after cardiac surgery. If the doctors caring for you during or after surgery do not give you platelets for bleeding then you will not be included in this research study.

Currently, platelets used for transfusion are stored at room temperature and can only be used for 5-7 days. However, some research in the lab suggests that platelets stored at a colder temperature may work better at stopping bleeding than platelets stored at room temperature and can be used for a longer period of time than platelets stored at room temperature, although it is not known whether the results will be the same in actual experience. The purpose of this research study is to compare the transfusion of cold-stored (refrigerated) platelets to standard room temperature stored platelets. The goal of the trial is to determine whether platelets stored cold are similar or better at stopping bleeding compared to platelets stored at room temperature and, if so, to determine the maximum duration of cold storage that maintains a similar effect on bleeding.

Cold-stored platelets are considered investigational for the purpose of this study, which means that it has not been approved by the U.S. Food and Drug Administration (FDA)..

In this study, the investigational cold stored platelets are stored for 7 days and may be up to 21 days. This will be the first clinical study to evaluate up to a 21 day cold storage period for platelets.

WHAT WILL HAPPEN DURING THIS STUDY?

You are being asked to participate in this study because you may receive a platelet transfusion during your operation or after your cardiac surgery. All study procedures will take place in the hospital operating room (OR) and/or Intensive Care Unit (ICU).

If you agree to participate, you will be randomly assigned to receive one of the 2 study treatments; either cold-stored platelets or standard room temperature platelets. This means that the study treatment you receive will be determined purely by chance. Patients will be randomly assigned in a 2:1 ratio to cold-stored and room temperature platelets. This means two out of every three patients will be randomized into cold platelet infusions while the third patient will be randomized into room temperature platelet infusions. Neither you nor the research team will know which study treatment you are receiving, but we will be able to get this information quickly if we need it for safety reasons. The study will start by using 7 days for cold storage of platelets for the first 200 patients, then the number of days allowed for cold storage will potentially change for each group of 200 patients enrolled after review of the safety information.

We will record information from your medical record such as date of birth, reason for transfusion, date of admission, date of discharge, vital signs, laboratory, and/or radiology results. We will also record information related to your medical/physical history, medication, treatments, and other clinical information.

We will collect blood samples prior to surgery, 30 minutes prior to the first platelet transfusion, and again 6 and 24 hours after the beginning of the first platelet transfusion to assess your bleeding risk and how well your kidney, heart and liver are functioning. If these blood samples are collected as part of your routine care, no additional blood samples will be collected. If these samples are not collected during your routine care then we may need to collect additional samples.

We will also be collecting information from your medical record about your response to the transfusions and your general medical condition.

Additionally, we will use information from your medical record to monitor your health during your hospitalization.

If you are discharged from the hospital prior to the end of the study, we will also contact you/your family/your doctor about 28 days after you join the study to see how you are doing if you have an adverse event during the study.

We will collect the following information while you are in the study:

- Weight, height, blood type, pre-operative condition, surgical history, physical status, and cardiac diagnosis.
- Surgical procedure data, including things such as: what type of surgery you had, the length of surgery, any surgical complications, and any assessments done during surgery or immediately after
- Blood product and platelet data
- Outcome data: any bleeding following surgery, any drainage coming out of your chest tube, other lab data that is collected from any research blood draws, or clinical blood draws obtained during your hospital stay.

Will you save my research information and/or biospecimens to use in future research studies?

- Identifiers will be removed from your private information including data/tissue/blood and used for future research or shared with others. If this occurs, we will not ask you for additional consent.

HOW MANY PEOPLE WILL PARTICIPATE?
This study will enroll up to 1,000 patients in 20-30 centers in the United States and 2 centers in Australia. A portion of these participants will be enrolled at this study site.

HOW LONG WILL I BE IN THIS STUDY?
If you agree to take part in this study, we will collect information from your medical records until you leave the hospital. We will also contact you/your family/your doctor about 28 days after you join the study to see how you are doing. Research records will be kept for at least 10 years after the end of the study.

****ALL SITES:** The following risk information from [START] through [END] cannot be altered without submission of supporting documentation and/or Sponsor approval of changes. Submitted changes will be reverted during Board review unless supporting documentation for the risk change is received

[START]

WHAT ARE THE RISKS OF THIS STUDY?
In this study, you will receive a blood product, platelets, that have been stored at room temperature or the same blood product that has been stored in the refrigerator for up to 21 days at 4 degrees Celsius (approximately 39 degrees Fahrenheit). There have been no known additional dangers of refrigeration of platelets when they have been given in the past for periods up to 14 days. There may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Some risks described in this consent document, if severe, may cause death.

For both room temperature and cold stored platelets, there is a possibility that both platelet products may not cause a clot as well and there could be increased bleeding from drainage tubes that are placed during surgery. If increased bleeding occurs this will be addressed by giving more blood products. If the bleeding is severe and the clinical team thinks that knowledge of which platelet was administered will impact their decision for your immediate care, they can ask to know what type of platelets was being given (cold or room temperature).

Risks of Transfusions
Platelet transfusions are considered to be well tolerated. However, there is a very small risk that any platelets (cold stored or room temperature stored) could contain viruses or parasites that could give you a disease. The risk of bacteria growing in platelets is higher in room temperature platelets, which are the current standard of care. Also, either platelet product (cold stored or room temperature stored) may contain small amounts of white blood cells from the donor. These white blood cells affect your immune system and increase your risk of infection.

The safety of cold stored platelets and the maximum length they can be stored is still to be determined and will be evaluated in this study. A potential risk is that cold stored platelets may cause more bleeding or blood clots than room temperature stored platelets, but this has not been seen in any previous studies of cold stored platelets.

Both cold stored and room temperature stored platelets have the following side effects including:

Uncommon reactions to platelets include:

- Nausea
- Chills
- Fever
- Drop in blood pressure
- Shortness of breath
- Itching and hives

On rare occasions, severe reactions could occur, resulting in:

- Lung injury
- Heart failure
- Allergic reaction that could even result in death
- Blood clots or blood not clotting as well
- Transfusion transmitted diseases
  - Blood banks screen donors for risk factors and test donated blood to reduce the risk of transfusion transmitted diseases, but they still very rarely occur (for example, less than 1in 1,500,000 for HIV)
- Transfusion-associated graft-versus-host disease
  - When white blood cells in the donor blood attack the cells in your body, it is called transfusion-associated graft-versus-host disease. This disease can be fatal. Signs and symptoms may include fever, rash, diarrhea, and abnormal liver function test results.

[END]

- Risk of Blood Draw
  - The potential risk of a blood draw can be minor discomfort and bruising, however to avoid this we will attempt to draw blood from an existing intravenous line or at the time of a medically necessary procedure so you will not need to have any additional needle sticks for research purposes. The blood that your nurse or health care professional need to take for your ICU care takes priority over any blood drawn for research. We will not draw blood for the study if your doctor or nurse tells us that taking the extra blood for research might be unsafe for you.

Breach of Confidentially
One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

However, we hope that in the future, other people might benefit from this study because information gained from the study may contribute to the advancement of medical care for patients who are bleeding due to cardiac surgery.

WHAT OTHER TREATMENT OPTIONS ARE THERE?
You may receive standard of care room temperature stored platelets without being in this study. Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?
As a part of this study you will receive tests and procedures that are similar to what you would receive during routine clinical care of your condition. Your health plan/insurance company will be billed for some or all of these costs, and you will be responsible for any co-pays and deductibles that are normally required by your health plan/insurance. Not all insurance plans cover the costs associated with being in a study. Even if they do, you may be responsible for more out of pocket expenses, such as co pays and deductibles, when there are more tests and procedures or more expensive tests and procedures involved in the study than if you were to receive routine clinical care outside the study.

If you wish to know whether there are more tests and procedures or more expensive tests and procedures in the study, you should ask your study doctor.

If you wish to know whether your insurance will pay, you should contact them directly, or speak with the study team about obtaining a financial pre-certification prior to enrolling in the study.

WILL I BE PAID FOR PARTICIPATING?
You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?
The Department of Defense (DoD) is funding this research study. This means that the study site is receiving payments from The DoD to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from The DoD for conducting this study.

Your specimens (even if identifiers are removed) may be used for commercial profit. You will not share in this commercial profit.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?
University of Pittsburgh and the study site investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the sponsor, Philip C. Spinella, MD at (412) 383-5235.

Your insurance may be billed for this treatment. Decisions about whether payment will be offered by the Sponsor for medical treatment for injuries relating to your participation in research will be made by

University of Pittsburgh. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of those records could contain information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- The Department of Defense (DoD)
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- WCG IRB, the Institutional Review Board that reviewed and approved this research (a committee that oversees the conduct of research involving human participants)
- Your PHI may be shared with the CHIPS study team and their representatives and the Data Coordinating Center at the University of Utah for the purpose of data processing, oversight, analysis, and the Medical Monitor and the Data Safety Monitoring Board (DSMB) for the purpose of safety oversight.
- The Medical Monitor is a qualified physician that will be designated to review and assess all serious adverse events reported from site investigators.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will de-identify your information by assigning your information a unique study ID. No one except members of the research team will be able to link your name to the study ID.

The primary data will come from information contained in your medical record related to your illness. In order to extract the relevant information, study staff will review the data from the medical record in the directory list and then record it into the secure database. The database will not contain any identifiers.

The data will only be identifiable through a linked code corresponding to the original directory, which will be kept separate from the research data, so that it may be linked back to the directory list if necessary. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

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

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the research team.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research.
- For sites in California, Delaware, Indiana, Illinois, and Washington, this permission will be good until December 31, 2070. For all other states, this authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
- To revoke your authorization, please contact your local research team at the number on the first page of this consent form.
    - **If you revoke your authorization:**
        - The research team may only use and share information already collected for the study.

- Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
- You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study.

If you withdraw from the study, we will ask your permission to continue to collect study data and safety related data through 28 days, discharge from the hospital, or death.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator, the study sponsor, or your doctor might decide to end your participation in this research study earlier than planned. This might happen for no reason or because it is in your best medical interest.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: the research team at the phone number(s) listed in this document. If you experience a research-related injury, please contact: the research team at the phone number(s) listed in this document.

If you have questions, concerns, or complaints; or questions about your rights as a research participant, please contact the WCG IRB at 855-818-2289 or clientcare@wcgclinical.com. General information about being a research participant can be found on the WCG IRB web site, https://www.wcgclinical.com/solutions/research-participants/. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the WCG IRB at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

All adult subjects unable to consent are required to assent, unless the investigator determines that the capability of the subject is so limited that the subject cannot reasonably be consulted. If assent is obtained, have the person obtaining assent document assent on the consent form.

All children are required to assent, unless the investigator determines that the capability of the child is so limited that the child cannot reasonably be consulted. If assent is obtained, have the person obtaining assent document assent on the consent form.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

_____	_____
(Signature of Participant)	(Date/Time)
_____	
(Participant's name – printed)	

Parent/Guardian Name and Relationship to Participant:

_____ (Child's name – printed)	
_____ (Signature of Parent/Legal Guardian)	_____ (Date/Time)
_____ (Name of Parent/Legal Guardian - printed)	_____ (Relationship to participant - printed)

Legally Authorized Representative's Name and Relationship to Participant:

_____ (Participant's name – printed)	
_____ (Signature of Legally Authorized Representative)	_____ (Date/Time)
_____ (Name of Legally Authorized Representative printed)	_____ (Relationship to participant - printed)

Who should sign as the Legally Authorized Representative (LAR)?
If the participant has a legal guardian or attorney-in-fact this individual must sign as the LAR.

If there is no legal guardian or attorney-in-fact the individuals listed below may sign in order of priority.

(1) Spouse unless the participant has no spouse, or is separated, or the spouse is physically or mentally incapable of giving consent, or the spouse's whereabouts is unknown or the spouse is overseas;
(2) Adult child;
(3) Parent;
(4) Brother or sister;
(5) Relative by blood or marriage.

Statement of Person Who Obtained Consent/Assent

The information in this document has been discussed with the participant or, where appropriate, with the participant's parent/legal guardian/legally authorized representative. The participant (if able) has indicated that they understand the risks, benefits, and procedures involved with participation in this research study. The participant's parent/legal guardian/legally authorized representative has agreed to the participant's participation in the study.

_____ _____

(Signature of Person who Obtained Consent/Assent) (Date/Time)

_____

(Name of Person who Obtained Consent/Assent - printed)

****For Sites in California****

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?
The study doctor and the study staff. They may also share the research information with an agent for the study doctor, if applicable.

Who might get this information?
The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- The institution where the research is being done,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Institutional Review Board (IRB)

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
This permission will be good until December 31, 2070.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Authorization:
I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

AUTHORIZATION SIGNATURE:

_____ _____

Signature of Participant/Parent/Legal Guardian/LAR **Date**