INFORMED CONSENT FORM
For Donor Participation in a Clinical Research Study

TITLE OF RESEARCH PROJECT

Evaluation of the Performance of Trima Accel® Version 7.0 Software Enhancements for the Collection of Platelets Stored in 100% Plasma

SPONSOR

Terumo BCT, Inc.
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PRINCIPAL INVESTIGATOR

< Insert name and contact information>

You are being asked to take part in a clinical research study being sponsored by Terumo BCT Inc, hereafter referred to as Terumo BCT. Clinical research studies are also called clinical trials. Clinical research is the process of studying the safety and effectiveness of medications, medical devices or treatments. You are being asked to take part in this study to provide blood products by apheresis, for the improvement of devices used in the collection of products for transfusions. In order to decide whether or not you want to participate in this study, you should understand the risks and benefits of the research and make an informed decision. This process is known as informed consent.

This consent form gives detailed information about the research study, which the study team will discuss with you. Please read this entire document and ask the study team as many questions as you want so that you understand what being a donor in this research study will involve. You should not join this research study until all of your questions are answered. Dr. <Insert Name of Site PI> is the Principal Investigator for this study at <Insert Name of Institution>. Once you understand the study and the other options that are available, you will be asked to sign this form if you wish to be in this study. You will be given a signed copy of this form to keep.

Your participation in this research study is entirely voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are entitled. You may withdraw from the study at any time without penalty. If you decide to participate, you are free to withdraw your consent and to leave the study at any time without penalty to you. You will not receive any direct benefits from this study.

WHY IS THIS STUDY BEING DONE?

You are being asked to be in this study because you are a healthy person. You are being asked to take part in a research study to provide blood products by apheresis, for the improvement of devices used in the collection of blood products used for transfusions. Apheresis is a process of collecting and separating blood into its components: platelets, plasma, and red blood cells. These methods are described in more detail later in this consent form.

These collections will take place on the Trima Accel system, which has been approved by the U.S. Food and Drug Administration (FDA). Researchers want to gather additional information on the Trima Accel for minor experimental software changes intended to improve collections that have not been approved by the FDA. These software changes should not cause any significant risk to you because the FDA-approved safety parameters for the overall Trima Accel system are never changed and any blood collection kits used have been approved by the FDA.

The software changes may improve the time of the procedure, the quality of the platelet products, and vein access during the procedure. Your chances of having any combination of the software changes during your apheresis procedure are based on the total blood volume in your body and the type of procedure you are undergoing.

Your participation in this study will last about 180 minutes and the study visits may occur on 1 or 2 days. This entire study will last about 16 months.

WHAT IS A CLINICAL TRIAL REGISTRY?

A description of this clinical trial will be available on 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.

HOW MANY DONORS WILL TAKE PART IN THE STUDY

Up to 350 subjects will participate in the study at up to 8 sites.

WHAT ARE THE STUDY PROCEDURES?

Screening

If you can be in the study and if you are interested in being in the study, you will be asked to sign this informed consent form. After you sign the informed consent form, screening procedures will be done. Screening procedures may occur within 30 days before the apheresis procedure. Screening procedures will take about 30 minutes.

You will complete a donor history questionnaire and be asked questions about your medical history and any medications you are taking or have recently taken. In certain cases, there will be restrictions for medications that affect platelet function prior to donating, and you will be told about those at the time of consent. You will have a brief clinical examination to check vital signs, including your blood pressure, pulse, and temperature.

You will have a finger pricked to get a drop of blood.

You may have a blood sample drawn from a vein in your arm (approximately 4 tablespoons) prior to your procedure.

If you qualify based upon the finger stick and/or laboratory result, vital signs and medical history, you will undergo an apheresis procedure.

Apheresis Procedure

The apheresis procedure starts with a needle being placed into a vein in your arm so that blood can flow from you into the Trima Accel machine.

After you are connected to the Trima Accel machine, a blood sample will be taken from the Trima collection bag for testing. This sample consists of about three tablespoons of the first blood flowing into the Trima Accel machine. There are two parts to the testing: A complete blood count, which makes sure you have a normal number of blood cells on the day of the collection and to verify if you qualify for a single, double, or triple platelet donation (if you did not have the blood drawn from your arm).

During apheresis, parts of your blood are separated and collected into blood product bags; the remainder of your blood is returned to you through the same needle.

The Trima Accel limits the amount and the type of blood products that can be taken from you by using calculations based on your height, weight, platelet and hemoglobin or hematocrit (a measure of red blood cells) counts. Between 1 and 4 cups of your blood will be collected during the procedure. For this research, only platelets and/or platelets with plasma will be collected. No red blood cell products will be collected.

You will be connected to the Trima Accel machine for about 90 minutes but no more than 150 minutes. You will be unable to bend your arm, get up, or move about freely during the collection procedure.

At the end of the collection, the needle will be withdrawn from your vein and you will be asked to hold pressure for a few minutes on the place where the needle entered. A bandage will be applied and the study staff will ensure that you feel well enough to leave the clinic. This will complete your visit and your participation in the study. If it is found that any of your laboratory values are abnormally high or low, Dr. XXXX or one of his/her designees will contact you.

The platelet product you donate during this study will not be used for transfusion and it will be destroyed at the end of the study.

WHAT ARE THE POSSIBLE DISCOMFORTS OR RISKS?

Finger stick

It is expected that the side effects of this procedure may include:

- Fear and pain;
- Minor bleeding under the skin and bruising;
- Infection.

Venipuncture (placement of the needle into your vein for blood draw and apheresis)

It is expected that the side effects of this procedure may include:

- Fear—very common, happens about 1 time in 5 procedures;
- Pain and discomfort, bleeding under the skin causing bruising, paleness, light-headedness, dizziness, nausea, sweating— common, happens less than 1 time in 10 procedures;
- Faintness—uncommon, happens less than 1 time in 100 procedures;
- Nerve irritation, infection—rare, happens less than 1 time in 1000 procedures;
- Arterial puncture, skin allergies, numbness, weakness and pain in hands and feet—very rare, less than 1 time in 10,000 procedures;
- Serious inflammation and blood clots—so rare that there have only been a few reported cases.

Apheresis Procedure

You will be unable to bend your arm during the apheresis procedure and you should avoid strenuous use of your arm for the remainder of the day.

To keep your blood from clotting while connected to the machine, you will be administered anticoagulant through the machine in the blood that is returned to you.

Trima disposable tubing sets are sterilized with ethylene oxide and, in very rare cases, may cause allergic reactions. Allergic reactions may include hives, faintness, or shortness of breath.

Similar procedures have been performed on the Trima system many times on many donors without serious problems.

It is expected that the side effects of the apheresis procedure may include:

- Tingling sensations in face and hands due to the anticoagulant used– very common, happens about 1 time in 5 procedures;

- Light-headedness, faintness, sweating, nausea, general weakness, and/or unpleasant taste due to the anticoagulant——common, happens less than 1 time in 10 procedures;

- Chills, cramps, spasms, vomiting, low blood pressure, which may result in loss of consciousness–uncommon, happens less than 1 time in 100 procedures;

- Tetany (periodic painful muscular spasms and tremors due to lowered blood calcium levels), seizures, convulsions, slow heart movement—rare, happens less than 1 time in 1000 procedures;

- Abnormal heart beat and loss of consciousness with physical injury—very rare, happen less than 1 time in 10,000 procedures;

- Heart attack, destruction of red blood cells, breathing difficulty, severe problems with circulation, air in your blood stream, and severe allergic reaction—so rare that there have only been a few reported cases.

Some other donor reactions that have been previously reported for automated collection procedures are hyperventilation, fever and headache.

If you have any of these side effects, please tell the staff immediately.

There is a small chance that a significant amount of your blood (approximately 1 cup) cannot be returned to you.

On rare occasions, the procedure can lead to a need for extended medical treatment, permanent impairment, and can be fatal.

POTENTIAL ADDITIONAL RISKS (RELATING TO SOFTWARE MODIFICATIONS)

There are no additional risks related to the software modifications in this trial.

WHAT ARE YOUR RESPONSIBILITIES?

By taking part in this research study you agree to the apheresis procedure. You agree to report any adverse reactions to the study doctor or study staff.

WHAT ARE THE POSSIBLE BENEFITS OF THE STUDY?

This study is designed for the Sponsor to learn more about blood collection and processing. This study is not designed to treat any illness or to improve your health. Information learned through this study may benefit others in the future.

ARE THERE ALTERNATIVES?

Your alternative is not to be in this study.

WHO IS PAYING FOR THIS STUDY?

This research is being paid by the Sponsor, Terumo BCT, the manufacturer of the Trima Accel collection device. A representative from Terumo BCT may be present during your donation to monitor, train or manage research operations.

WILL I HAVE TO PAY FOR ANYTHING?

It will not cost you anything to be in the study.

WILL I BE PAID FOR BEING IN THIS STUDY?

You will be paid for each completed donation of blood during this study.

Platelets	$

It is important to know that payments for participation in a study may be taxable income. A check will be mailed after the completion of your procedure.

WHAT WILL HAPPEN IF I AM INJURED IN THIS STUDY?

In the event of an injury or illness resulting from your participation in this research study, the site will assist you in receiving appropriate health care, including first aid, emergency treatment and follow-up care either at the site or another appropriate health care facility. If you experience an illness, side effect, or injury that is the result of the device, intervention, or procedure required for this study the Sponsor of the study, Terumo BCT will pay usual and customary medical fees for reasonable and necessary treatment that have not been covered by your insurance, a government program, or other third party coverage. The Sponsor is not responsible for expenses that are due to pre-existing medical conditions, underlying disease, or your negligence or willful misconduct. In addition, the Sponsor will not pay for expenses that result from site's negligence, misconduct or failure to follow the study protocol. The study doctor and the Sponsor will determine if the adverse event or injury was a result of your participation in this study. Financial compensation for lost wages and other non-medical costs will not be available. By signing this form you have not given up your legal rights.

You should inform your care provider(s) if you decide to participate in this research study. If you have questions about injury related to the research, you may call <Insert PI's Name> at <Phone #> and your private physician. If you believe you have experienced any study related illness, adverse event, or injury, you must notify the study doctor as soon as possible.

WILL YOUR INFORMATION BE CONFIDENTIAL?

During the study, all records that identify you will be kept confidential. Your information will not be made publically available except under certain circumstances required by law.

The following groups or people will have access to your information, including your original medical records and data collected during the study. By signing this form you are allowing these people to see your records and use the collected data.

- The Sponsor or representatives of the Sponsor, such as consultants or vendors. This includes staff that will process, analyze and store data from the study. They will monitor study progress and they will check to see that the data being collected is correct.

- The Institutional Review Board and FDA or other regulatory authorities: People from these groups will check that the data are accurate and that the study is conducted properly.

Although the people listed above are allowed to see your original medical records, the data collected for this study will not identify you. Your data will be given an ID code that can only be traced to your name by the study doctor and his/her staff.

The information collected in this study will be used for reports for regulatory authorities, like the FDA. The data may also be used in scientific reports and presentations and for future medical research. You will not be identified in any published report of this study.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

Your participation in this study is entirely voluntary and you can refuse to participate. If you decide to participate, you can withdraw your consent and stop taking part in the study at any time. You will not be penalized and you will not lose any benefits to which you are otherwise entitled. In addition, the study doctor or the Sponsor can terminate your participation in the study at any time for any reason. If there are significant new findings that occur as a result of the study, you will be informed of those results so that you can make a decision whether you are willing to continue to participate in the study. If you have questions about your Rights, please contact <insert IRB contact> at <insert IRB phone #>.

WHO SHOULD YOU CONTACT FOR QUESTIONS?

If you have questions about the study, or if you experience any side effects, you may contact the study doctor, Dr. <insert name of PI>, at <insert phone number> any time.

If you have any questions about your rights as a research subject, you may contact the <insert name of IRB> Institutional Review Board at <insert phone number>.

STATEMENT OF CONSENT

Donor:

I have read, or someone has read to me, this informed consent form which describes the purpose and nature of this research. I have had time to review this information and I have had the opportunity to ask questions. All of my questions have been answered to my satisfaction. I understand that I may contact the people listed above if I have additional questions. I understand the possible risks and benefits of this study, alternative treatments and my rights as a participant. I know that I can stop participating in the study at any time and I will not lose any benefits or any of my legal rights and I will still receive the usual medical care. I agree to take part in this study and complete all the required tests and procedures. I agree that samples of my blood may be stored for additional testing if needed. I agree that in the event that I withdraw my consent to participate, information gathered about me during my participation can still be used for research purposes. I give my permission to have my medical records reviewed in connection with this study. I understand that my participation in this study is completely voluntary and my signature below indicates that I give my consent. I acknowledge that I have received a signed and dated copy of this consent form for my records and future reference.

_____
Donor's Printed Name

_____ _____
Signature of Donor Date

PERSON OBTAINING CONSENT

I acknowledge that I have discussed the study with the donor and answered all of his/her questions. In my judgment, the donor understands the information and has voluntarily agreed to participate in the study.

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date