

## **Informed Consent for Leukapheresis Collection**

Form # 08-15

### **Description of Procedure**

We will collect some of your blood cells in a procedure called "leukapheresis". You will have IVs inserted, one in each arm. If a special central venous catheter is needed, that will be discussed separately by your research team. The blood is taken out of one arm and run through a machine that collects only the cells we want. The rest of your blood is given back to you in the other arm. The entire collection process takes up to 7 hours, depending on how many cells are needed.

### **Risks of Procedure**

You may experience the side effects listed below while undergoing the collection of white blood cells. These reactions or side effects are usually reversible when the procedure is stopped or with the correct medical care:

- A sterile anticoagulant solution is used to prevent your blood from clotting in the machine. The anticoagulant works by binding to calcium in your blood. You may experience tingling of your lips or fingers, a "vibrating" sensation, or more rarely, nausea, vomiting or muscle tightness. To counteract these possible symptoms, we give replacement calcium to you by vein during the procedure. If these symptoms occur despite replacement calcium, more calcium will be given until symptoms resolve.
- You will receive about 1 to 2 quarts of anticoagulant solution by vein during each collection procedure. If you have a history of heart failure or kidney disease, you may retain some of this fluid, causing increased weight or swelling in your hands or feet. A large volume of extra fluid may cause shortness of breath. These symptoms can be treated with diuretics.
- The anticoagulant solution contains dextrose (sugar). If you have diabetes, you may require extra insulin to keep your blood sugar level within the desired range.
- Low blood pressure, high blood pressure or slow pulse may occur as a result of blood being moved through the machine. If these occur, the procedure will be slowed or stopped until symptoms resolve.
- Blood pressure medicines called Angiotensin Converting Enzyme (ACE) inhibitors should not be taken before your collection procedure. These medications may cause low blood pressure during your collection procedure. If you are on an ACE inhibitor, your physician may prescribe an alternate blood pressure medication.
- Some blood platelets (cells in the blood involved in clotting) are removed during stem cell collection. If your platelet counts drop very low, you may need to receive a platelet transfusion to prevent bleeding.

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**Informed Consent for Leukapheresis Collection- continued**

- Your red cells and plasma may not be returned to you if there are any problems with needle placement in your veins or with the apheresis equipment. A decreased red blood cell count may occur as a result. However your counts should return to normal within 4 weeks. If your blood counts are extremely low, you may need to receive a red cell transfusion to prevent symptoms.
- Some patients with a history of migraine can have return of their migraine headaches with therapy. If you have a migraine history, notify your physician and you will be treated with magnesium by vein to help prevent migraines.
- Although extremely rare, serious or life-threatening reactions are possible and include allergic reactions, infections, seizures, air embolism or arrhythmias (abnormal heart rhythms). We will carefully monitor you for these and if they begin, we will immediately stop the procedure and treat you accordingly.

***Signature***

I confirm that the purpose of the leukapheresis collection procedure and the possible risks and discomforts that I may experience have been explained to me. All my questions have been answered. I have read and understand this consent form. My signature below indicates my willingness to participate in this collection procedure.

\_\_\_\_\_  
*Subject/Donor*

\_\_\_\_\_  
*Date*

\_\_\_\_\_  
*Legal Guardian/Representative*

\_\_\_\_\_  
*Date*

I have explained the purpose of the collection procedures, the possible risks and discomforts and have answered any questions regarding the collection procedure to the best of my ability.

\_\_\_\_\_  
*Signature of Provider (MD/NP/PA)*

\_\_\_\_\_  
*Date*