

PENNSTATE



Cancer Institute

at Penn State Milton S. Hershey Medical Center



## Penn State Milton S. Hershey Medical Center

### CONSENT FOR OPERATION OR OTHER PROCEDURE

Condition For Which Treatment is Proposed: Autologous Stem Cell Collection

1. I authorize my physician/practitioner, \_\_\_\_\_ (name) and/or such other staff physicians or resident physicians as my physician may designate, to perform upon me (or the patient identified above) the following operation or procedure (for procedures on all paired organs or extremities, the side of the body must be specified as left, right or bilateral, without abbreviations: Use of Mozibil and Neupogen for Autologous Stem Cell Collection.

I understand that physicians designated by my physician, including but not limited to physicians in the Penn state Milton S. Hershey Medical Center post graduate residency program, may be performing important tasks related to my surgery in accordance with Penn State Milton S. Hershey Medical center policy and, in the case of resident physicians, based on their skill set and under the supervision of an attending physician.

It has further been explained to me that qualified medical practitioners who are not physicians may also perform important parts of my surgery or administer the anesthesia, but only to the extent such tasks are within their scope of practice, as determined by Pennsylvania law, and for which they have been granted privileges by Penn State Milton S. Hershey Medical Center.

In this consent form, the operation or procedure identified above is referred to as the "procedure". I understand that at the time of my procedure, circumstances may require changing which individual practitioners are involved in performing the procedure.

2. My physician/practitioner has discussed with me the items that are briefly summarized below:

- (1) The description of the proposed therapy: I will undergo the following test and procedures to determine if I am eligible for this procedure: Complete medical history and physical examinations, blood test for blood cell counts, blood chemistries, clotting test, liver and kidney functions, test for certain communicable diseases including but not limited to test for HIV/AIDS and an electrocardiogram to check the heart.

I will not be able to participate in the procedure if I am pregnant or nursing. If I am a female and capable of having children, I will have a serum pregnancy test (blood test) performed. If I think I could be pregnant at any time during the treatment, I will inform my doctor immediately.

I will receive a drug called granulocyte colony-stimulating factor (G-CSF) as daily subcutaneous injections (shot under my skin) continuing until completion of the hematopoietic cell collection. G-CSF is a drug to increase my white blood cells (infection-fighting cells). These white blood cells also contain cells used in marrow transplantation called hematopoietic cells. I understand that I will have daily blood tests drawn while I am receiving the G-CSF, and prior to each leukapheresis procedure to obtain the hematopoietic cells. In this procedure, my white blood cells and hematopoietic cells will be collected by a technique called leukapheresis. In order to perform leukapheresis, two needles will be inserted in my veins, or if I have poor veins, a central line catheter will be inserted into a vein in my chest. I understand that I will be asked to sign a separate

## SPECIAL CONSENT FOR OPERATION OR OTHER PROCEDURE

Patient ID Label

consent form for the insertion of a central line. Each leukapheresis procedure will take approximately 4 hours to complete, and will be repeated (in order to obtain the necessary number of peripheral hematopoietic cells). During each leukapheresis procedure, I will also receive an infusion of calcium gluconate intravenously over 15 minutes at one hour and at three hours into the infusion. This is due to a possible decrease in my blood level of calcium during the leukapheresis.

I will receive a drug called Mozobil® (plerixafor injection) as a subcutaneous injection in combination with G-CSF therapy. Mozobil is a hematopoietic stem cell mobilizer used to mobilize stem cells to the peripheral blood for collection.

- (1) (2) The material risks of the proposed procedure, including the risk that this treatment may not accomplish the desired purpose: The risks of the proposed procedure, including the risk that this treatment may not accomplish the desired purpose: It has been explained to me that the following risks and consequences are involved in this procedure and are listed below. The side effects of G-CSF are usually mild and short-lived; and include muscle aches, pain in the bones, rash or worsening of rashes or skin disorders that may already be present. Rarely, blood clots may form in a central venous catheter. Growth factors may make an ongoing or established infection worse by overactivating some white blood cells, and cause elevation of alkaline phosphatase (an enzyme found in the bones and in the liver). G-CSF may also cause fever or chills, headache, loss of appetite, tiredness, and sweating, although these side effects do not occur frequently. I may also experience some redness of the skin at the place where the G-CSF is injected. G-CSF also may worsen or bring on a case of gout. In rare cases, the G-CSF can cause enlargement and sometimes rupture of the spleen. Calcium Gluconate may cause a tingling sensation with intravenous use and possible fainting, mild decreased blood pressure, chalky taste, and vein irritation with rapid IV injection.

The common side effects of Mozobil are diarrhea, nausea, vomiting, fatigue, redness and swelling at injection site, pain in your joints, headache, and dizziness. Most side effects may improve or disappear after you finish Mozobil injections. Less common, but possible side effects include abdominal pain and swelling, excessive sweating, dry mouth, redness of skin, stomach discomfort, constipation, indigestion, muscle or bone pain, a reduced sensation to stimuli such as touch, general feeling of being unwell, or sudden drop in blood pressure when standing from a sitting position. It is possible that Mozobil may increase the number of white blood cells, a condition called leukocytosis, or decrease the number of circulating platelets (thrombocytopenia). Rarely, an allergic reaction to Mozobil could happen, these reactions may include light-headedness and/or difficulty breathing. Mozobil may increase the size of your spleen, a condition called spleen enlargement, which could potentially cause spleen rupture. Signs of enlarging spleen include pain in your upper left-hand region of your abdomen or near the tip of your shoulder. I am aware that I should notify my physician immediately if I have symptoms of this life-threatening condition.

Possible risks associated with the use of central venous catheters include puncturing my lung, bleeding, decreased blood pressure and infection. Risk of the Peripheral Blood Hematopoietic Cell Harvest: Leukapheresis: Cytopenia (low blood counts) and anemia may occur. Anemia is from a low red blood cell count and the symptoms could include paleness of my skin, weakness and tiredness. Patients undergoing leukapheresis may experience signs of citrate toxicity which could include paresthesia (sensations of numbness, prickling or tingling), abdominal discomfort and nausea/vomiting.

- (3) The medically reasonable alternative treatment: Not to collect Stem Cells.
- (4) What may happen if the proposed procedure is not performed: Transplant will not be performed.

**SPECIAL CONSENT FOR OPERATION OR OTHER PROCEDURE**

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3. I am aware that, in addition to the risks specifically described above, there are other risks that are present with respect to any surgical procedure, such as severe loss of blood, infection, risks associated with anesthetic administration, cardiac arrest, and blood clots lodging in the lungs, any of which may require additional corrective surgery or result in death.
4. I understand that during the course of this procedure, unforeseen conditions may arise which could require the nature of my procedure to be altered, or that another operation or procedure be performed. I therefore authorize my physician, or other physicians designated by my physician, to provide such medical treatment, or perform such operation or procedures as are necessary and desirable in the exercise of professional judgment.
5. It has been explained to me that there may be circumstances when information must be disclosed or report pursuant to law, such as if it is determined during the course of the procedure that I have tuberculosis, viral meningitis, or other diseases required to be reported to state and/or federal authorities such as the Pennsylvania Department of Health or Centers for Disease Control and Prevention.

It has been explained to me that my medical information will be kept confidential in accordance with the policies of Penn State Milton S. Hershey Medical Center.

6. I understand the goals and anticipated benefits of the proposed procedure and the likelihood of achieving those goals. I am also aware that the practice of medicine and surgery is not an exact science, and I acknowledge that no guarantees have been made to me concerning the results of the proposed procedure.
7. I agree to receive blood or blood products (red cells, platelets, plasma, cryoprecipitate, or granulocytes) if this need arises during my surgery. I understand that transfusions are not risk-free, although blood is carefully tested. The risks of transfusion include, but are not limited to: 1) fever, hives, or shaking chills; 2) infections: Hepatitis B, Hepatitis C, HIV (the AIDS virus), bacterial contamination/infection, and other, unknown infections; 3) reactions from a mismatch of blood types; and 4) transfusion associated lung injury (TRALI).  
  
I understand that a transfusion can always be refused. The risks of not receiving transfusion therapy have been explained to me. I understand that receiving my own blood may be a possibility which I should discuss with my doctor.
8. I acknowledge that the information I have received, as summarized on this form, is sufficient for me to consent to and authorize the procedure described above. I have had the opportunity to ask questions concerning my condition, and about the procedure, alternatives and risks, and all questions have been answered to my satisfaction.
9. I impose the following limitation(s) regarding my treatment (if none, so state): \_\_\_\_\_  
\_\_\_\_\_

10. I authorize the staff of The Penn State Milton S. Hershey Medical Center to preserve for scientific or teaching purposes any tissues or parts which may be removed in the course of this procedure, and to dispose of them.

