

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: Cyclophosphamide and Etoposide chemotherapy for Autologous Stem Cell Mobilization)

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 is to administer chemotherapy (drugs to fight my cancer, which may also have other effects on my body) by mouth and/or by vein.

(2) The material risks of the proposed chemotherapy:

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**Chemotherapy** may cause nausea, vomiting, loss of appetite, mouth sores, hair loss, fatigue, a lowering of the white blood cell count (which can lead to a serious infections), a lowered platelet count (which can lead to bleeding), and a decrease in my red blood cell count (which can lead to shortness of breath, a rapid heartbeat or weakness). Due to these low blood counts, I may require red blood cell or platelet transfusions. My doctor will give me appropriate medications to try to decrease the severity of any side effects. Other side effects could occur, rarely death. It is important that I call my physician or nurse-coordinator with problems which occur during the course of my treatment. I always have the right to refuse chemotherapy at any time. It is possible that this chemotherapy may not be effective and my disease might progress.

**Long-term side effects** of chemotherapy can include injury to lungs, heart, liver and/or bladder. Acute leukemia can also develop as a result of chemotherapy.

**Chemotherapy usually has an adverse effect on sperm and eggs** and can cause me to be unable to have children. Chemotherapy can have harmful effects on an unborn child. If I am a woman, it is important to tell my physician if I think I may be pregnant. It is possible to conceive a child during treatment with chemotherapy. It is important that both men and women who are being treated with chemotherapy and who are sexually active, fertile, and who have a fertile partner use a reliable form of birth control (birth control pills, a reliable barrier method or a hormonal implant.)

You (or the patient for whom you consent) may require venipuncture (putting a needle into a vein to remove blood or administer chemotherapy). **The discomfort associated with venipuncture** is a slight pinch or pinprick when the sterile needle enters the skin. The risks of venipuncture include mild discomfort and/or a black or blue mark at the site of the needle puncture. Less commonly, a small blood clot, infection or bleeding may occur at the needle puncture site. When chemotherapy is administered into a vein, there is also a small risk of either infection in the bloodstream or the chemotherapy leaking outside the vein causing tissue irritation or damage.

**The drugs which will be used for my planned chemotherapy and their specific side-effects:**

**Cyclophosphamide:** There is a small chance of causing urinary bladder (where urine is stored) irritation. This bladder irritation can cause pain and the appearance of blood in urine. However, this is almost always avoidable by drinking 8 to 10 glasses of water a day and emptying my bladder every 2 to 3 hours for 3 days, especially before bedtime. A metallic taste in the mouth and nasal congestion are commonly experienced immediately after the administration of the drug. Rarely, prolonged administration of the drug has been reported to cause scarring of the lungs which could cause me to experience coughing spells and shortness of breath and may not be reversible. Rarely, there may be severe or life-threatening allergic reactions.

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**Etoposide** may cause decreased energy, skin rash, pain and inflammation at infusion site, and temporary low blood pressure. There is a potential of a build up of fluid around the heart. Vision problems, including blindness, headache, dizziness, confusion are rare side effects associated with Etoposide. Other side effects include muscle cramps, a decrease in the function of my nervous system, decreased kidney function, increased blood pressure, excess acidity throughout the body due to abnormal metabolism, allergic reactions, weight loss, abdominal pain, constipation, aftertaste, difficulty in swallowing, swollen glands, increased levels of certain chemicals in the liver, a change in the color of my skin. In rare cases, acute leukemia may develop after treatment with Etoposide

(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.

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.

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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.
11. I authorize The Penn State Milton S. Hershey Medical Center to permit other persons to observe the procedure with the understanding that such observation is for the purpose of advancing medical knowledge. I understand that for certain procedures, representatives of device manufacturers may be present. I authorize the presence of such industry representatives if my physician believes it is appropriate. I further authorize Penn State Milton S. Hershey Medical Center to obtain photographic or other pictorial representations of the procedure, and to use such representations for scientific or teaching purposes.
12. I certify that all blanks requiring insertion of information were completed and any questions I had have been answered before I signed this consent form.

\_\_\_\_\_ provided the information summarized above and obtained the consent for the procedure.

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Patient's Signature (or signature of person consenting on behalf of the patient)      Date      Time      PM      AM

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
\*Optional – Witness to Patient's Signature      Date      Time      PM      AM

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Physician/s/Practitioner's Signature      Date      Time      PM      AM

This consent is valid for up to 60 days from the date of the patient's signature unless there is significant change in the patient's condition or consent is revoked by the patient.

\*Use of a witness is at the discretion of the individual obtaining the consent.