

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: **Allogeneic Bone Marrow Donor**

1. I hereby authorize my physician/practitioner, \_\_\_\_\_, 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): **Allogeneic Bone Marrow Harvest.**

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) 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, chest X-ray, and an electrocardiogram to check the heart.

I will not be able to participate in the procedure if 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 have the right to see all my test results.** The doctor will discuss these results with me. I give informed consent and authorization to release my health information to the transplant physician and/or the recipient as appropriate.

Patient ID Label

- (2) The description of the proposed procedure: I have been informed that a family member has a disease for which a hematopoietic cell transplant is part of the indicated treatment. I understand that as part of the treatment, my relative will receive high-dose chemotherapy, and my relative's normal bone marrow will be destroyed. I have been asked to donate bone marrow. I understand that while under anesthesia in the operating room, a mixture of bone marrow and blood will be withdrawn through a needle inserted through the skin into the hip bones, and perhaps, the breast bone. I understand that 2-4 pints of blood and bone marrow may be taken; that is considered safe. In the event that red blood cells have to be removed from the bone marrow and cannot be given to the recipients, these red cells will be returned to me.
  - (3) The material 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 risks and benefits of the bone marrow aspiration have been explained to me. A risk associated with general anesthesia consists of breathing difficulties or changes in my heart rhythm that could be fatal. This risk is less than 0.1%. There is a small risk that an infection could develop at the needle puncture sites. I understand there is a small risk of excessive bleeding at the needle puncture sites. I may experience pain or soreness at the needle puncture sites that may last as long as a week. I understand that blood transfusions may be given to me as part of the procedure. This carries a small risk of developing a transfusion reaction or hepatitis and there remote risk of developing the acquired immunodeficiency syndrome (AIDS). My bone marrow may react against my family member and cause an illness known as graft-vs-host disease (GVHD). GVHD may be fatal to my family member. I understand that these effects do not mean that my marrow is bad or that the problems are any fault of mine. The removal of my bone marrow may directly benefit my family member in the treatment of his/ her disease.
  - (4) I understand that my participation in my relative's treatment is voluntary, and I am free to withdraw at any time. Refusal to participate in or withdrawal from this procedure will involve no penalty or the loss of benefits to which I am otherwise entitled, and will not prejudice future care of my family member. **However, after my relative has received the intensive chemotherapy, I do understand that hematopoietic cell transplantation is a life-saving measure that must be undertaken.**
  - (5) The medically reasonable alternative treatments: This transplant could be performed using peripheral blood hematopoietic stem cells as the source of cells for the transplant. Also, it has been explained to me that the patient's condition could be treated with different drugs or drug combinations including other chemotherapy regimens.
  - (6) What may happen if the proposed procedure is not performed: My relative may not be able to receive a hematopoietic cell transplant.
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.

Patient ID Label

5. It has been explained to me that there may be circumstances when information must be disclosed or reported 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 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.

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.

**Patient ID Label**

\_\_\_\_\_ 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      AM  
PM

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

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

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.