

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: _____

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): High dose chemotherapy with Cyclophosphamide and Busulfan and Matched related Allogeneic Hematopoietic Stem Cell Transplantation.

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 procedure: To destroy the disease with chemotherapy. This also destroys the bone marrow. The marrow will be replaced by transplantation of hematopoietic stem cells obtained from a family member whose bone marrow matches mine very closely. Tacrolimus and methotrexate will be used to prevent rejection and graft-versus-host disease (GVHD).

- (2) The material risks of the proposed procedure, including the risk that this treatment may not accomplish the desired purpose:

Rejection can occur in 2% where a related donor is fully matched and in 5 to 15% in situations where the donor is not fully compatible with the recipient of the transplant.

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GVHD (Graft Versus Host Disease) Differences between donors can result in GVHD in almost all of the patients when the donor is outside of the family or is partially matched. The disease occurs when certain blood cells (T-lymphocytes) from the marrow of the donor begin to function in my body. These T-cells sense my body as “foreign” (not exactly like the tissue from the donor), and begin to attack my tissue causing problems. This is a natural function of T-lymphocytes but one which needs to be properly controlled to have a successful transplant. There are two types of graft-versus-host disease; acute and chronic. Acute graft-versus-host disease occurs in the first 100 days following hematopoietic cell transplant and may cause skin rash, liver dysfunction, diarrhea, and/or fever, increased risk of severe infection, and possibly death. Graft-versus-host disease is called chronic if it persists or develops more than 100 days after transplant. It can cause skin discoloration, damage to the mouth resulting in ulcers, corneal ulceration (an ulcer of the cornea off my eye), dry eyes, dry mouth, liver damage, shortness of breath, cough, respiratory failure, inability to digest food, stiffness in joints and muscles, hair loss, increased risk of severe infection and possibly result in death. Graft-versus-host disease can be controlled by drugs, but these are not always successful. Uncontrolled graft-versus-host disease can result in death.

Busulfan may cause changes in skin color, scarring of the lungs, infertility, sore mouth, seizures, yellow skin from liver damage, and elimination of all normal bone marrow function. Damage to the heart leading to heart failure, bleeding from the bladder, rash, and damage to the lungs leading to shortness of breath may occur. In rare cases, acute leukemia may develop after treatment with busulfan, especially when it is given with other anticancer drugs.

Cyclophosphamide will cause a decrease in my blood cell count which could cause a potentially life-threatening infection or episode of bleeding. Other side effects include nausea, vomiting, hair loss, irritation of the bladder, metallic taste, headache, nasal congestion, possible scarring of lung tissue, absence of my menses (periods) (females), and possible liver and heart damage with high doses. Acute leukemia has developed in some patients treated with cyclophosphamide, although this is rare.

Tacrolimus (Prograf®) frequently causes diarrhea, trouble sleeping, headache, abdominal pain, tremors (involuntary movements), fatigue, increased levels of magnesium and potassium in the blood, increased blood sugar, high blood pressure, nausea, vomiting, numbness or tingling in my hands or feet, and low blood cell counts which could cause easy bruising, abnormal bleeding, and/or anemia (from a low red blood cell count; symptoms of anemia include paleness of my skin, weakness and tiredness). Other common side effects include possible liver damage, loss of appetite, increased white blood cell count, back pain, and excess fluid in the body (ascites). Less common side effects include swelling of the ankles and feet, constipation, skin rash, musculoskeletal pain, blurred vision, decreased urine output, urinary tract infection, hair loss, sensitivity of the eyes to light. Rarely increased appetite, sweating, ringing in the ears, dizziness, nightmares, hair growth, and chest pain can occur.

Methotrexate commonly causes a decrease in white blood cells and platelets, leading to an increased risk of infection or bleeding, sore mouth, diarrhea, hair loss, nausea and vomiting. Less common side effects include scarring of the liver, pneumonia, skin rashes, itching and changes in the coloring of the skin.

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G-CSF: The side effects of G-CSF are usually mild and short-lived, and include muscle aches, bone and joint pain, 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 over activating 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 may also worsen or bring on a case of gout.

Peripheral Blood Hematopoietic Cell Transplantation:

- Peripheral hematopoietic cell infusion may be associated with volume overload, pulmonary emboli, allergic reaction including fever, chills, and hives, abdominal cramps, sudden decrease or increase in blood pressure, slow heart rate, transient heart rhythm changes, and hypoxemia (not enough oxygen to the cells in the body).
- Failure to engraft resulting in death from bleeding, and/or infection can occur in 5 to 15% of patients.
- Death from complications can occur in 30 to 40% of patients.
- Following the transplant, I may develop acute or chronic graft-vs-host disease (GVHD). Even though all measures are taken to ensure that my marrow and that of my donor are compatible, slight differences may remain. If this occurs, my new bone marrow may look at my body as “foreign”. If this occurs in the first 100 days after transplant, it is known as acute GVHD, and can result in a severe skin rash with peeling or loss of skin, failure of my liver leading to hepatitis, and/or yellowing of my skin and eyes, nausea, loss of appetite, and severe diarrhea. Acute GVHD occurs in most transplant patients. Chronic GVHD develops 100-450 days after the transplant in 80% of patients. Symptoms of chronic GVHD include dry eyes and mouth, difficulty swallowing, skin rash, thickening and tightening of the skin, and frequent infection. Drugs are available to treat this condition. They cure chronic GVHD 33% of the time and result in improvement in most other patients.
- **It is possible that decreasing GVHD could increase the risk of relapse of my malignancy**
- Failure of the immune system including cancers of the immune system.

Since information about my medical condition will be sent to the Center for Blood and Marrow Transplant Research, there is also a risk of loss of confidentiality if this information is obtained by someone other than these organizations, but precautions will be taken to prevent this from happening.

I understand that my donor’s participation in my treatment is voluntary, and that the donor is free to withdraw at any time. After I have received the intensive chemotherapy, I do understand that hematopoietic cell transplantation is a life-saving measure that must be undertaken. My donor will be advised of this risk.

- (3) The medically reasonable alternative treatment is: Standard dose chemotherapy or no chemotherapy at all until the disease progresses again.
- (4) What may happen if the proposed procedure is not performed: The disease may eventually progress.

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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 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.

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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.

_____/_____/_____ AM
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

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.