PENNSTATE
Cancer Institute
at Penn State Milton S. Hershey Medical Center

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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): Full matched related donor non-ablative 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: This treatment will use the chemotherapy drugs fludarabine and cyclophosphamide at low doses to suppress or inhibit the immune system (cells and substances that protect our body from infection and foreign matter). You will then receive a transplant of hematopoietic stem cells (cells that are responsible for establishing bone marrow and blood production) from a matched volunteer related donor. You will also be given the immunosuppressive drugs tacrolimus and methotrexate to support the transplant before and after the procedure. The purpose of this treatment is to use the immunologic effect of the transplant in controlling your Disease.

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

Treatment often has side effects. There is substantial discomfort from the side effects of this treatment, and a definite risk of dying from these side effects**.** Specific drugs used in this procedure have the following risks:

Fludarabine may suppress the normal bone marrow function and lower the blood counts. In rare cases, brain damage has occurred, though almost always when the dosage has been higher than used here.

Cyclophosphamide will cause a decrease in your 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 your 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.

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.

Tacrolimus (FK-506) 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 your 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 your 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, muscle and bone 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.

The side effects of **G-CSF (Neupogen)** 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. You 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.

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Risks of Peripheral Blood Stem Cell Transplantation:

- Peripheral stem cell infusion may be associated with too much fluid in your body, blood clots in the lung, allergic reaction including fever, chills, and hives, abdominal cramps, sudden decrease or increase in blood pressure, slow heart rate, temporary changes to your heart rhythm, and hypoxemia (not enough oxygen to the cells in the body).
- Failure to engraft can occur in 5 to 15% of patients. If this occurs, you should recover with adequate function of your own bone marrow within 4 weeks.
- Death from complications can occur in 30 to 40% of patients.
- Following the transplant, you may develop acute or chronic graft-versus-host disease (GVHD). Even though all measures are taken to ensure that your marrow and that of your donor are compatible, differences may remain. If this occurs, your new bone marrow may look at your 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 your liver leading to hepatitis, and/or yellowing of your 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 many 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.
- Failure of the immune system including cancers of the immune system.
- Risk of therapy being worse than other treatments or not as good as standard care.

It is possible that the donor stem cells will not grow in your body after the transplant. If this happens, your own stem cells should recover promptly and start to grow again in your body. Also, it is possible that the low doses of chemotherapy drugs used in this study may be less effective than other alternative treatments.

Risks of bone marrow biopsy may cause pain and tenderness at the needle insertion site. Also, potential bleeding and infection could also occur at the needle site.

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 treatments: 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.

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.

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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: Hepatits 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.

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_____ provided the information summarized above and obtained the consent for the procedure.

AM

_____ _____/_____/_____ _____PM

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

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.

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