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: Germ Cell Carcinoma

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 Etoposide and Carboplatinum and Autologous Hematopoietic Stem Cell Transplantation given in two cycles.

   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 Germ Cell Carcinoma with chemotherapy. This also destroys the bone marrow. The marrow will be replaced by transplantation of my own stem cells obtained previously from me and stored by freezing.

   (2) The material risks of the proposed procedure, including the risk that this treatment may not accomplish the desired purpose: The stored cells may fail in growing back my bone marrow. This can result in death from infection or bleeding. Even if the marrow grows back, there is a risk of severe infection, bleeding, pneumonia, liver failure, lung failure, heart failure, leukemia. The Germ Cell cancer may return.

   Chemotherapy can cause Nausea and Vomitting.

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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, weigh 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.

Carboplatin may cause numbness and tingling in the fingers and/or feet, an allergic-like reaction, changes in taste, rare decrease in kidney function, decrease in hearing or ringing in the ears. Blood counts may take longer to recover. There may be a decrease in certain salts in the body (magnesium, potassium, and calcium).

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).

(3) The medically reasonable alternative treatments: Standard dose chemotherapy or no chemotherapy at all until the Germ Cell Carcinoma progresses again.

(4) What may happen if the proposed procedure is not performed: The Germ Cell Carcinoma will 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.

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.

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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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