

Revised: 1/2016

Consent for Chemotherapy/Biotherapy, **Larson -- all phases**

Condition for which treatment is proposed: _____

1. I hereby authorize my physician, Dr _____, and/or such other staff physicians or resident physicians as my physician may designate, to administer to me (or the patient for whom I consent) the following chemotherapy consisting of:

Cyclophosphamide
Daunorubicin
Vincristine
Prednisone
Asparaginase

Cytarabine
6-Mercaptopurine
Thioguanine
Methotrexate

The plan for my course of treatment is for _____ cycles of therapy, with each cycle given about every _____ days.

The goal(s) of this treatment is (are) to:

_____ 1. Become free of my cancer with the hope that it will not return.
provider initials

_____ 2. Slow the progression of my cancer, relieve my symptoms and help prevent future
provider initials problems from my cancer.

2. My physician has discussed with me the items that are briefly summarized below:

- a. The nature and purpose of the proposed therapy is to administer **chemotherapy/biotherapy** (drugs to fight my cancer, which may also have other effects on my body) by mouth and/or by vein or by other type of injection. **Chemotherapy** usually refers to drugs which directly kill cancer cells, **Biotherapy** refers to either drugs which change my immune system to better fight my cancer or antibodies (so-called targeted treatments) which bind to cancer cells and help kill them. Sometimes several types of agents are combined in a plan of therapy. It is possible that this therapy may not be effective and my disease might progress.



- b. **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 heart beat 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 therapy at any time.
- c. The side effects of **Biotherapy** agents are often different from the side effects of chemotherapy drugs and depend on which agents I will receive. These are listed below by each drug.
- d. **Chemotherapy long-term side effects** can include injury to lungs, heart, liver and/or bladder. Acute leukemia can also develop as a result of chemotherapy.
- e. **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.)
- f. **Venipuncture:** You (or the patient for whom you consent) may require venipuncture (putting a needle into a vein to remove blood or administer treatment). 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 therapy is administered into a vein, there is also a small risk of either infection in the bloodstream or the drug leaking outside the vein causing tissue irritation or damage.

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

Cyclophosphamide may cause a metallic taste in the mouth immediately after the administration of the drug. Cyclophosphamide causes urinary bladder (where urine is stored) irritation that may lead to pain and the appearance of blood in the urine and rarely leads to permanent bladder damage. Cyclophosphamide may also cause headaches, dizziness, nasal congestion, allergic reactions, hair loss, possible heart problems, or liver abnormalities, and temporary imbalance of my salt and fluid status. I could experience a hot feeling and lightheadedness for a few minutes after the drug is given in the vein, but this rapidly disappears.

Danuorubicin can cause local skin rash, irregular heart beats, kidney and liver problems, temporary red urine, and potential heart damage. Tissue damage may occur if it leaks outside the vein. In rare cases, acute leukemia may develop after treatment with daunorubicin, especially when it is given along with other anticancer drugs.



Vincristine can cause numbness and tingling in the hands and feet, with possible difficulty walking and performing fine motor task, rash, abdominal pain, constipation, increased liver chemicals possibly indicating liver damage, seizures, headaches, blindness, severe pain in the jaw, face, throat, extremities, bones, back and limbs, muscle weakness. Other side effects include coughing, skin and soft tissue damage, vision problems and kidney problems.

Prednisone may cause an irritation of the stomach lining (possibly leading to an ulcer bleeding), high blood pressure, high blood sugar (or the aggravation of existing diabetes), serious infections and delayed wound healing, elevated white blood count, decrease in blood sodium, increased appetite, weight gain, rash, skin thinning, facial hair growth, acne, facial redness, bruises, menstrual changes, difficulty sleeping, muscle weakness, wasting, mood changes, seizures, fluid retention and swelling, cataracts, increased pressure behind the eye and bone weakening, viral, bacterial and fungal infections, including herpes and tuberculosis. More common with short-term use are stomach upset and insomnia.

Asparaginase can cause allergic reactions that can be mild (rash) and rarely severe of life-threatening (shortness of breath, bleeding abnormalities, abdominal pain, depression, dizziness, hallucinations (ranging from mild to severe), headaches, irritability, throat constriction, fluid retention, a decrease in blood pressure, an increase in certain gasses in the kidney, fatigue, liver test abnormalities, and inflammation of the pancreas. If an allergic reaction occurs, PEG-Asparaginase given intramuscularly or Erwinia Asparaginase given intravenously may be used.

Cytarabine can cause weight loss, difficulty in swallowing, kidney problems, flu-like symptoms, rash, headache, blindness, seizures, the sensation of tingling or creeping on the skin, inflammation of the eye, skin rash, and mild liver damage. Loss of balance and coordination is usually temporary when it occurs, but is occasionally more long-term. Higher doses can cause significant nausea. Death to brain tissue is also a possibility.

6-Mercaptopurine can cause skin problems, rash, yellowing of the skin and eyes, a change in the color of the skin, death to skin cells; abdominal pain, changes in liver tests, and headache. Irritation can result if the drug leaks onto the top layer of the skin.

Methotrexate can cause dilation of blood vessels, vomiting blood, dark tarry stools, lung problems and coughing, malaise, blurred vision, watery eyes and eye inflammation, blindness, liver injury, kidney damage, inflammation of the lung, osteoporosis, excess acid in the urine and allergic reactions. Methotrexate may also cause various skin problems, which may include skin redness irritation and rashes, changes in the color of my skin, acne, blisters, and swelling and inflammation of the skin and/or hair follicles. It also may cause a peculiar sensitivity to sunlight. Methotrexate may cause alterations in brain structure (though this is less common with administration into the spinal fluid), tiredness, dizziness, weakness, confusion, difficulty in coordination, tremors, irritability, seizures, headache, back pain, stiff neck, paralysis, and coma. Other side effects include a decreased bone mass in the legs.

Thioguanine can cause liver damage, mouth sores, elevated uric acid which could lead to gout, and damage to the intestines which could lead to a perforation of the bowel.

3. I am aware that, in addition to the risks specifically described above, there are other risks that are present with respect to any treatment.



4. I understand that during the course of this treatment, unforeseen conditions may arise which could require the nature of my treatment to be altered.
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 treatment 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.
6. I understand the goals and anticipated benefits of the proposed treatment 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 treatment.
7. I acknowledge that the information I have received, as summarized on this form, is sufficient for me to consent to and authorize the treatment described above. I have had the opportunity to ask questions concerning my condition, and about the treatment, alternatives and risks, and all questions have been answered to my satisfaction.
8. I impose the following limitation(s) regarding my treatment (if none, so state):

9. I authorize the staff of 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 treatment, and to dispose of them.
10. I authorize Penn State Milton S. Hershey Medical Center to permit other persons to observe the treatment with the understanding that such observation is for the purpose of advancing medical knowledge.
11. I certify that all blanks requiring insertion of information were completed before I signed this consent form.

_____ provided the information summarized above and obtained
 (fill in name) the consent for the procedure

_____/_____/_____
 (Patient's Signature) (Date) (Time)
 (or signature of person consenting on behalf of the patient)

_____/_____/_____
 (Optional: Witness to Patient's Signature) (Date) (Time)

_____/_____/_____
 (Physician's Signature) (Printed name) (Date) (Time)

MR 1234 11/08



