

Consent For Hyper CVAD (courses 1 & 2)

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
Doxorubicin
Vincristine
Dexamethasone
Methotrexate
Cytarabine (High-dose)**

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

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 (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.
 - b. The risks of the proposed chemotherapy:

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 chemotherapy at any time. It is possible that this chemotherapy may not be effective and my disease might progress.

Long-term side effects of chemotherapy can include injury to lungs, heart, liver and/or bladder. Acute leukemia can also develop as a result of chemotherapy.

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.)



You (or the patient for whom you consent) may require **venipuncture** (putting a needle into a vein to remove blood or administer chemotherapy). 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 chemotherapy is administered into a vein, there is also a small risk of either infection in the bloodstream or the chemotherapy leaking outside the vein causing tissue irritation or damage.

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

Cyclophosphamide: There is a small chance of causing urinary bladder (where urine is stored) irritation. This bladder irritation can cause pain and the appearance of blood in urine. However, this is almost always avoidable by drinking 8 to 10 glasses of water a day and emptying my bladder every 2 to 3 hours for 3 days, especially before bedtime. A metallic taste in the mouth and nasal congestion are commonly experienced immediately after the administration of the drug. Rarely, prolonged administration of the drug has been reported to cause scarring of the lungs which could cause me to experience coughing spells and shortness of breath and may not be reversible. Rarely, there may be severe or life-threatening allergic reactions.

Doxorubicin may cause heart damage when used for prolonged periods of time or in high doses. Due to the red color of doxorubicin, my urine may turn red for 1 to 2 days after I am given the drug; but this is harmless. Also seen is darkening of the nail beds and skin. In rare cases, the fingernails can become loose.

Vincristine may cause constipation, urinary retention (difficulty urinating), nerve damage (numbness in the fingers or toes) which may be severe and permanent, unstable gait, loss of deep tendon reflexes, muscle aches, temporary blindness (rare), seizures, pain in the jaw, temporary salt and fluid imbalance, fever and rarely inflammation of the pancreas.

Dexamethasone can cause loss or increase of appetite, weight gain, aggravation of ulcers, rash, facial hair growth, acne, bruising of the skin, redness of the face, menstrual changes, headache, loss of sleep, dizziness, depression, psychosis, a sense of well being, seizures, muscle weakness, fluid retention, an increase in blood pressure, irritation or inflammation of the veins, increased pressure in the eyes, cataracts, a change in metabolism, an increase in white blood cells, back pain, osteoporosis (loss of calcium from the bone tissue resulting in bones that break easily), viral, bacterial and fungal infections, including herpes, delayed wound healing, muscle wasting. This drug could cause abnormal reactions to skin tests. Other side effects include a protrusion of the eyes and skin cell death.

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.



Cytarabine (High-dose) may cause weight loss, difficulty in swallowing, kidney problems, flu-like symptoms, 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 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.

3. The medically reasonable alternative treatments and the risks associated with these alternative treatments have been described by my physician. These alternatives include no treatment, combinations of different chemotherapy drugs, or the same drugs given in different doses or on a different schedule.
4. Without the proposed treatment, my disease may progress, it could remain stable or, rarely, improve.
5. I understand that during the course of this chemotherapy, unforeseen conditions may arise which could require the planned chemotherapy to be altered. All alterations to the planned chemotherapy will be discussed with me.
6. I am aware that the practice of medicine is not an exact science, and I acknowledge that no guarantees have been made to me concerning the results of the proposed therapy.
7. I acknowledge that the information I have received, as summarized on this form, is sufficient for me to consent to and authorize the chemotherapy described above. I have had the opportunity to ask questions concerning my condition, the chemotherapy, the 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 The 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.
10. I authorize the Milton S. Hershey Medical Center to permit other persons to observe this procedure with the understanding that such observation is for the purpose of advancing medical knowledge. I authorize The Milton S. Hershey Medical Center to obtain photographic or other pictorial representations of this procedure, and to use such representations for scientific or teaching purposes.
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 the
(fill in name) 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)

(Date)

