

Consent For **CLAG-M**

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:

**Filgrastim (G-CSF)**  
**Mitoxantrone**

**Cladribine**  
**Cytosine Arabinoside**

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:**

#### **Mitoxantrone**

May cause reversible elevations in liver blood tests, irregular heartbeats (which usually reverse to normal in 48 hours) and when given in high doses over a period of time has the potential to cause heart weakening or failure. Other side effects include itching, dry skin and bluish green discoloration of the urine and stool for 24 hours after the drug is given. Allergic reactions, damage to the liver, cough, shortness of breath, fever and conjunctivitis have also occurred rarely.

#### **Cladribine**

Can cause fatigue, rash, headache, these reactions were usually mild to moderate in severity.

#### **Cytosine Arabinoside**

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.

#### **Filgrastim (G-CSF)**

The side effects of G-CSF are usually mild and short-lived; and include muscle aches, pain in the bones, 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 also may worsen or bring on a case of gout.

3. The medically reasonable alternative treatment and the risks associated with these alternative treatments have been described by my physician. These alternative include no treatment, combinations of different chemotherapy drugs, or the same drug 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, 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 therapy 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 therapy, 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)

