PENNSTATE HERSHEY
Cancer Institute

Consent for CALGB REGIMEN for ALL (Larson etal); 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	**Cytarabine**
Daunorubicin	**6-Mercaptopurine**
Vincristine	**Thioguainine**
Prednisone	**Methotrexate**
Asparaginase	

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 the vein, there is also a small risk of either infection in the bloodstream of the chemotherapy leaking outside the vein causing tissue irritation or damage.

The drugs which will be used for my planned chemotherapy 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 rearly 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 of Erwinia Asparaginase given intravenously may be used.

Cytarabine can cause weight loss, dufficulty 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 occationally 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. Methorexate 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 peculian 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.

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 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)