PENNSTATE HERSHEY
Cancer Institute

Consent For CHOP-RITUXIMAB
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
   Prednisone
   Rituximab

   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.

Prednisone may cause an irritation of the stomach lining (possibly leading to an ulcer which can bleed), 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.

The specific side-effects of rituximab are:

Likely reactions

Reactions which may occur as the drug is being given include fever, chills and/or nausea which can be severe.

Less Likely reactions:

- High blood pressure.
- Low blood pressure.
- Abnormal fast heartbeat.
- Skin rashes or hives.
- Itching.
- Allergic reaction that may cause fever, aches and pain in the joints, skin rash and swollen lymph

glands.

- Excess sweating or flushing.
- Cough, shortness of breath or wheezing.
- Stuffy or runny nose, sneezing.
- Swelling of the lips, eyes, tongue and throat which can be severe.
- Swelling of the arms or legs.
- Pain in the area of the tumor.
- Severe hepatitis (liver infection) in those patients who are carriers of the hepatitis virus. Your doctor **may** screen you for the hepatitis virus before beginning treatment. If you test positive for the virus, you will be closely monitored for signs of the infection.
- Some other viral infections may be worsened or reactivated from a "sleeping" state in patients taking rituximab.

Rare, but serious side effects

- Another viral infection, like those mentioned above, causes a serious brain condition called progressive multifocal leukoencephalopathy (PML). PML can be serious, causing severe disability or death.
- Skin rash that may be severe.
- Severe reactions during rituximab infusions or severe allergic reaction: A fast heart rate, wheezing, low blood pressure, sweating, swelling of the throat and face rash may occur within a few minutes of starting treatment. They can be handled with medications and sometimes by slowing the rate of infusion. The reactions are more common during the first infusion of rituximab. You will be given medications to decrease the likelihood that the reactions may occur and decrease their severity if they should occur.
- Tumor Lysis Syndrome, a rapid decline in the number of tumor cells that can lead to kidney failure and/or chemical imbalances that may have an affect on other organs like your heart. If this were to occur, you would receive close monitoring and blood tests, as well as appropriate medical treatment.
- Severe lung dysfunction resulting in an inability to breathe which can be life-threatening.
- Potentially life-threatening condition affecting less than 10% of the skin in which cell death causes the epidermis (outer layer) to separate from the dermis (middle layer).
- Life-threatening condition affecting greater than 30% of the skin in which cell death causes the epidermis (outer layer) to separate from the dermis (middle layer).

Other Considerations

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, combination of different chemotherapy drugs, or the same drugs given in different does 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 purpose 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 consent for the procedure
(fill in name)

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

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

_____/_____ AM PM
(Physician's Signature) (Date)