PENNSTATE HERSHEY
Cancer Institute

CONSENT for Modified Folfiri w/ Cetuximab
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:

   1. Irinotecan
   2. Fluorouracil (5FU)
   3. Cetuximab (Erbitux)

   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:

   (1) 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.

   (2) 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:

1. **Irinotecan**: Diarrhea (which may be severe); cholinergic reaction (sweating, flushing, abdominal cramping or diarrhea) during infusion; increased risk for blood clots.

2. **Fluorouracil (5FU)**: Tenderness and soreness of palms of the hands and the soles of the feel, change in nail beds, increased sensitivity to sun, and darkening and hardening of the vein used for giving 5FU can occur. Diarrhea, mouth sores, fatigue, weakness, muscle aches, and headaches, chest pain, angina can also occur.

3. **Cetuximab:** acne type skin rash (most commonly occurs on the face, upper chest, and back could extend to the extremities and characterized by multiple pustular appearing lesions), radiation dermatitis(characterized by red, inflamed, and possibly peeling skin), changes in finger nails, itching, and conjunctivitis, and infusion reactions; flu-like symptoms, anaphylaxis

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)