PENNSTATE HERSHEY
Cancer Institute
1855

Consent for Pralatrexate (Folotyn®)
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 therapy consisting of:

   Pralatrexate (Folotyn®)

   The plan for my course of treatment is for _____cycles of therapy, 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 treatment is to administer therapy (drugs to fight my cancer, which may also have other effects on my body) by mouth and/or by vein.

   (2) The risks of the proposed treatment:

   It is unknown what effects this therapy may have on an unborn child in a pregnant woman, or any impact on your ability to have children in the future. For pregnant women, it is expected that there would be harm to the unborn child with this therapy. Please notify your doctor if you think you may be pregnant. It is important that both men and women who are being treated with these therapies 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 therapy is administered into a vein, there is also a small risk of either infection in the bloodstream or the therapy leaking outside the vein causing tissue irritation or damage.

The specific side-effects of Pralatrexate (Folotyn®) include:

Most Common (>10%)

- Fatigue
- Fever
- Nausea
- Vomiting
- Constipation
- Diarrhea

- Rash
- Itchiness
- Fluid retention
- Low blood counts (white blood cells, red blood cells, platelets)
- Abnormal liver function (determined by blood test that measures liver enzymes)
- Headache
- Back pain
- Cough
- Shortness of breath
- Night sweats

Less Common (1-10%)

- Dehydration
- Neutropenic fever
- Weakness
- Upper respiratory infection
- Increased heart rate
- Sepsis

Rare but serious (<1%)

- Bowel obstruction
- Heart attack
- Tumor lysis syndrome (Happens when a large tumor breaks down quicker than body can break down the dead tumor cells)
- Toxic epidermal necrolysis (detachment of upper layer of skin from lower layer of skin)

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 therapy 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 therapy, unforeseen conditions may arise which could require the planned therapy to be altered. All alterations to the planned therapy 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 therapy described above. I have had the opportunity to ask questions concerning my condition, the therapy, 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)