PENNSTATE HERSHEY
Cancer Institute

Consent for Nilotinib (Tasigna ®)
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 treatment consisting of:

Nilotinib (Tasigna ®)

The plan for my course of treatment is for _____months of therapy.

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 therapy (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)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.)

<u>The specific side-effects of Nilotinib (Tasigna ®) include:</u>

Most Common (>10%):

- Rash, itching of your skin
- Diarrhea
- Constipation
- Nausea/Vomiting
- Belly pain
- High blood sugar
- Fatigue
- Headache
- Fever
- Fluid retention
- Shortness of breath
- Cough
- Upper respiratory Tract infection
- Muscle weakness and discomfort
- Low blood counts (white blood cells, red blood cells, and platelets)

Less Common (1-10%):

- High blood pressure
- Abnormal heart rhythm
- Chest pain
- Flushing
- Depression
- Dizziness
- Insomnia
- Acne like rash, hair loss
- Diabetes Mellitus
- Belly pain
- Weight loss
- Neutropenic Fever (development of a fever in a person with other signs of an infection who has a low white blood cell count)
- Peripheral neuropathy (numbness and tingling in fingers and toes)
- Dry eyes
- Bleeding in eye
- Shortness of breath
- Pneumonia
- Night sweats
- Abnormal liver function (determined by blood test that measures liver enzymes)

Rare but Serious (<1%)

- Heart failure
- Heart attack
- Liver toxicity
- Kidney failure
- Hemorrhage (large amount of blood loss)
- Sepsis (whole body immune response to infection)

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 treatment, 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 procedure 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 procedure, 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)