PENNSTATE HERSHEY
Cancer Institute

Consent for **IVIgG**

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:

IVIgG

The plan for my course of therapy is for _____doses of IVIgG, with each dose 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 a preparation of immunoglobulins to replace deficient immunoglobulins or boost your immune system to help fight your disease.

   b. The risks of the proposed therapy:

   You (or the patient for whom you consent) may require **venipuncture** (putting a needle into a vein to remove blood or administer therapy). 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.

   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.)

The specific side-effects of IVIgG are: (% of patients give IVIgG who get a particular reaction)

Common reactions:

Heart and Blood vessels

- Heart murmur (6.6%)
- High blood pressure (6-7%)

- Low blood pressure (5-22%)
- Increased heart rate (6.4%)
- Increased systolic arterial pressure (6.4%)
- Swelling in the feet & ankles (8.2%)

Skin

- Injection site reaction (5-98%)
- Itching (6-8%)
- Rash (4.1-7.8%)
- Hives (5-8.2%)

Endocrine Metabolic

- Increased body temperature (9%)

Gastrointestinal

- Ulcers of mouth (6.4%)
- Diarrhea (6-28%)
- Nausea (5-26%)
- Upper abdominal pain (3.9-10.6%)
- Vomiting (6-23%)

Musculoskeletal

- Aches & pains in joints (3.9-12%)
- Muscle weakness (6.8%)
- Muscle pain (5-20%)
- Pain in limb (6.4-11.5%)
- Spasm (6-6.8%)

Nerves

- Weakening (5-10%)
- Dizziness (6-13.1%)
- Headache (8-61%)
- Lethargy (6%)
- Migraine (5-6.6%)

Ears

- Ear pain (6.4-18%)

Respiratory

- Wheezing 8.5-29%)
- Cough (6-26%)

- Nasal congestion (10-15%)
- Pain in throat (6.4-6.8%)
- Sinusitis (2-16%)

Other

- Dehydration (6%)
- Fatigue (5.9-24%)
- Fever (3-37%)
- Pain (6-13%)
- Shaking chill (13.1-37%)

Serious side effects

Heart & Blood vessels

- Chest discomfort (6.8-9%)
- Chest pain (7-11%)
- Heart attack
- Rapid heartbeat (22%)

Endocrine Metabolic

- Low blood sodium level

Hematologic

- Hemolysis
- Hemolytic anemia
- Thrombosis

Hepatic

- Liver inflammation

Immunologic

- Allergic reaction

Musculoskeletal

- Backache (3.9-28%)

Neurologic

- Inflammation of the membranes around the brain and spinal cord

Kidney

- Acute kidney failure

Respiratory

- Blood clots in the lungs
- Lung injury

- Shortness of breath

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 or combinations of chemotherapy drugs.

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

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) (Time)