Informed Consent for administration of Aranesp® - darbepoetin alfa for “Chemotherapy Induced Anemia”

What is the most important information I should know about Aranesp®?

What is Aranesp®?
Aranesp® is a man-made form of the protein human erythropoietin, which works by stimulating your bone marrow to produce new red blood cells. After two to six weeks of treatment, your red blood cell counts will hopefully increase, decreasing the need for blood transfusions and assisting with symptom management.

Aranesp® can cause serious side effects:

- Your doctor will use the lowest dose of Aranesp® needed to help you avoid red blood cell transfusions.
- Studies have shown that Aranesp® may increase tumor growth if given to patients with consistently high hemoglobin levels.
- Once you have completed your chemotherapy course, Aranesp® treatment will be discontinued.
- Aranesp® treatment may increase your chance of blood clots, which can form in blood vessels in your arms or legs. Please contact your physician if you experience any arm or leg pain with or without swelling and or redness.
- Blood clots may move from the legs to the lungs and block the blood circulation in the lungs (pulmonary embolus). Please contact your physician immediately or seek medical attention if you experience any shortness of breath, chest pain, or other respiratory symptoms that may concern you.

Call your doctor right away if you experience any of the following symptoms of a blood clot, while taking Aranesp®:

- chest pain
- shortness of breath
- pain in the legs with or without swelling

You will be asked to have blood tests that will check the number of red blood cells your body is producing. The blood tests will see if Aranesp® is working and if your hemoglobin level is getting too high. Your doctor may refer to the results of your blood tests as hemoglobin and hematocrit. The amount of time it takes to reach the red blood cell level that is right for you, and the dose of Aranesp® needed to make the red blood cell level rise, is different for each person. You may need Aranesp® dose adjustments before you reach your correct dose of Aranesp® and the correct dose may change over time. It is important to keep all appointments for blood tests to allow your doctor to adjust the dosage of Aranesp® as needed.

The Federal Drug Administration requires us to distribute a Medication Guide for Aranesp (Darbepoetin alfa). This Medication Guide was prepared by Amgen Pharmaceuticals, the manufacturer of Aranesp, at the request of the Federal Drug Administration.

I, __________________________, have been given the Medication guide for Aranesp (Darbepoetin alfa) and voluntarily consent to the administration of Aranesp (Darbepoetin alfa) for the purpose of production of red blood cells and maintenance of Hemoglobin and Hematocrit levels.

Dr. __________________________ and associates have explained to me that the drug may have beneficial effects as well as undesirable side effects.

___________________________  Date  ______________________  ______________
(Witness)   (Patient or responsible party)  Date