NATIONAL KIDNEY FOUNDATION MALAYSIA

Form B

INFORMED CONSENT FOR MEDICATION

I,_____, NRIC No. _____,

have been informed that my kidneys are not functioning and that I am suffering from Anemia. Anemia is a condition in which the body has fewer red blood cells than normal. Anemia commonly occurs in people with chronic kidney disease (CKD) and End Stage Renal Disease — permanent, partial loss of kidney function. Anemia might begin to develop in the early stages of CKD, when someone has 20 to 50 percent of normal kidney function. Anemia tends to worsen as CKD progresses. Most people who have total loss of kidney function, or kidney failure, have anemia.

When kidneys are diseased or damaged, they do not make enough Erythropoetin (EPO). Erythropoietin (EPO) is a hormone produced by the kidney that promotes the formation of red blood cells by the bone marrow. As a result, the bone marrow makes fewer red blood cells, causing anemia. When blood has fewer red blood cells, it deprives the body of the oxygen it needs. Erythropoietin will stimulate the bone marrow to produce more red blood cells. The resulting rise in red cells increases the oxygen-carrying capacity of the blood.

Other common causes of anemia in people with kidney disease include blood loss from hemodialysis and low levels of the nutrients found in food such as iron, vitamin B12 and folic acid. These nutrients are necessary for red blood cells to make hemoglobin, the main oxygen-carrying protein in the red blood cells.

The signs and symptoms of anemia may include weakness, feeling tired, headaches, problems with concentration, paleness, dizziness, difficulty breathing or shortness of breath and chest pain.

I understand that although haemodialysis will cleanse my blood, it cannot replace the function of producing EPO by my kidneys. If blood tests indicate kidney disease as the most likely cause of anemia, treatment can include injections of a genetically engineered form of EPO. I will receive an injection of erythropoietin (Micera) based on my Nephrologist's prescription under my skin once per month.

The following risks are associated with treatment with Micera, and while such risks are not common, one or more can occur.The possible side effects, risks and/or discomforts that may be experienced by patients receiving Micera include headache, body aches, diarrhea, or vomiting. If any of these effects last or get worse, I will have to inform my doctor promptly.

Micera may sometimes cause or worsen high blood pressure, especially in patients with long-term kidney failure. This effect may be caused by the number of red blood cells increasing too quickly, usually within the first 3 months of starting treatment. I understand that if I have high blood pressure, it should be well controlled before I begin treatment with this medication. My blood pressure should be checked often. If high blood pressure develops or worsens, I will follow my doctor's instructions about diet changes and start or adjust my high blood pressure medication. Lowering high blood pressure helps prevent strokes, heart attacks, and further kidney problems. I will keep all lab appointments to have my red blood cell count/hemoglobin level tested regularly to reduce the chance of this side effect.

I understand that rarely, this medication may suddenly stop working well after a period of time because my body may make antibodies to it. A very serious anemia can result. I will tell my doctor right away if symptoms of anemia return (such as increased tiredness, low energy, pale skin color, shortness of breath).

I will tell my doctor right away if I have any serious side effects, including: symptoms of heart failure (such as shortness of breath, swelling ankles/feet, unusual tiredness, unusual/sudden weight gain).

Rarely, this medication may cause serious (sometimes fatal) problems from blood clots (such as heart attack, stroke, blood clots in the legs or lungs). I will get medical help right away if I have: shortness of breath/rapid breathing, chest/jaw/left arm pain, unusual sweating, confusion, sudden dizziness/fainting, pain/swelling/warmth in the groin/calf, sudden/severe headaches, trouble speaking, weakness on one side of the body, sudden vision changes, blood clots in my hemodialysis vascular access site.

I understand that a very serious allergic reaction to this drug is rare. However, I will get medical help right away if I notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing, fast heartbeat.

I understand that the above is not the complete list of possible side effects. As such, if I notice other effects not listed above, I will contact my doctor.

I understand that it will be necessary for me to follow certain conditions during this treatment such as following up regularly with my referring Nephrologist to monitor my Hemoglobin and iron levels as well as monitoring of my blood pressure. It will be my responsibility to follow these conditions as failure to do so can cause complications to my health and disease. In addition, I understand that it will be my responsibility to take my other medications as prescribed by my Nephrologist.

Informed Consent :

I have read this consent (or it has been read to me) and I understand it. The form has been fully explained to me by a member of the health care professional. I had a chance to ask questions, and my questions have been answered to my satisfaction.

By my signature below, I GIVE consent for administration of Injection Micera at the prescribed dosage range.

My signature also indicates that I understand the following:

- I can refuse to give consent or I can withdraw my consent at any time with written notification to the National Kidney Foundation of Malaysia or by informing the Nurse-in-Charge of the Centre.

- Further questions regarding this medication can be discussed with the Interdisciplinary team, including my Nephrologists.

- My consent permits the dose of medication to be changed by my Nephrologist based on my hemaglobin level without signing another consent.

- I understand the reasons for the use of the medication, its potential risks and benefits, and the probable consequences that may occur if the proposed medication is not given.

- I have read this consent (or it has been read to me) and I understand it. The form has been fully explained to me by a member of the health care professional. I had a chance to ask questions, and my questions have been answered to my satisfaction.

- This consent is for a period effective immediately and not to exceed twelve (12) months from the date of my signature. The need for and continued use of this medication will be reviewed at least quarterly by my referring Nephrologist.

I voluntarily consent to accept this medication treatment and authorise the staff to provide this service to me.

_____ Date: _____ Time: _____

Signature/Thumb Print of Patient

Name :_____

NRIC No: _____

_____ Date: _____ Time: _____

Signature/Thumb Print of Witness

Name : _____

NRIC No: _____

_____ Date: _____ Time: _____

Signature of Physician

Name: _____

Chop: