NATIONAL KIDNEY FOUNDATION MALAYSIA

Form B

INFORMED CONSENT FOR MIRCERA MEDICATION

I,_____, NRIC No. _____,

have been informed that my kidneys are not functioning well and that I am suffering from anaemia. Anaemia is a condition in which the body does not have enough healthy red blood cells to carry adequate oxygen to the body's tissues. Anaemia might begin to develop in the early stages of chronic kidney disease (CKD) and tends to worsen as CKD progresses. When kidneys are diseased or damaged, they do not make enough Erythropoietin (EPO). Erythropoietin is a hormone produced by the kidneys that promotes the formation of red blood cells by the bone marrow. As a result, the bone marrow makes fewer red blood cells, causing anaemia. Other common causes of anaemia in people with kidney disease include blood loss, low levels of essential nutrients (such as iron, vitamin B12 and folic acid), chronic infections, inflammatory problems and bone marrow disorders. The signs and symptoms of anaemia may include weakness, feeling tired, headaches, cold intolerance, problems with concentration, paleness, dizziness, difficulty in breathing and chest pain.

I understand that I have been assessed by my Nephrologist who has recommended Erythropoietin treatment of my anaemia. I understand that my Nephrologist has prescribed Mircera because he or she has judged that the benefit to me is greater than the risk of side effects. I agree to receive an injection of erythropoietin (Mircera) administered subcutaneously every month based on my Nephrologist's prescription.

I understand that Mircera treatment can have the following side effects, and while such side effects are not common, one or more can occur:

1. Worsening of hypertension: Mircera may sometimes cause or worsen high blood pressure. I understand that if I have hypertension, it should be well controlled before I begin treatment with this medication. I understand that I shall follow my nephrologist's recommendation of antihypertensive medications intake and monitor my blood pressure regularly. I understand that I shall return to my Nephrologist for further review if my blood pressure is not well controlled.

2. Seizures: Seizures have occurred in CKD patients participating in Mircera clinical studies. I understand that I shall seek medical attention immediately if I develop any seizure or premonitory symptoms.

3. Serious Allergic Reactions: 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, or fast heartbeat.

4. Pure Red Cell Aplasia: 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 anaemia can result. I will tell my nephrologist right away if symptoms of anaemia return (such as increased tiredness, low energy, pale skin color, shortness of breath).

5. Severe Cutaneous Reactions: I understand that some patients may develop swelling and pain at the injection site of Mircera. I shall notify my Nephrologist if I develop any severe skin reaction to Mircera.

6. Blood clots, strokes and heart attacks: I understand that this medication may rarely 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 develop 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 haemodialysis vascular access site.

7. Other possible side effects: I understand that some patients receiving Mircera treatment may develop headache, body aches, diarrhoea, or vomiting. If any of these effects last or get worse, I will have to inform my doctor promptly.

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 immediately.

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 Haemoglobin 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. 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 profession. 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 Mircera 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 haemoglobin 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: _____