INFORMED CONSENT FOR TREATMENT WITH REMICADE

REMICADE (infliximab) is approved by the US Food and Drug Administration (FDA) for treatment of Crohn's disease and ulcerative colitis. REMICADE is a synthetic antibody that binds to tumor necrosis factor (TNF), part of the body's inflammatory system, and inactivates TNF. Because it inactivates TNF, REMICADE is called an "anti-TNF antibody" (or "anti-TNF" for short). By blocking TNF, REMICADE may reduce inflammation in patients with Crohn's or ulcerative colitis and thus improve symptoms.

WARNINGS:

REMICADE may reduce symptoms from Crohn's or ulcerative colitis; however, the medication has been associated with side effects, including serious side effects with the potential to cause death.

Immediate infusion reactions within a few hours of infusion can include fever, chills, chest pain, low blood pressure, high blood pressure, difficulty breathing, rash (including hives), and itching. More common infusion reactions are sinus congestion, sore throat, headache, cough, and stomach pain; these usually go away within 24 hours.

Delayed infusion reactions – with symptoms including skin rash, joint pains, muscle pains, and fatigue– have been observed within a few days after infusion, especially in patients who are restarting REMICADE after a period of time off the medication.

Serious infections, including bacterial (and mycobacterial), fungal, and/or viral infections, can occur at any time in patients on anti-TNF medications like REMICADE (or can be made worse by the use of REMICADE) because anti-TNF medications like REMICADE lower the ability of your immune system to fight infection. Mycobacterial infections can include tuberculosis (TB). Other bacterial infections can include infected joints, listeriosis, and Legionella pneumonia (also known as Legionnaire's disease). Fungal infections can include including histoplasmosis, coccidiodomycosis, Cryptococcus, aspergillosis, and pneumocystis pneumonia. Viral infections include hepatitis B and Herpes zoster. The risk of serious infection is increased if you are on other drugs that suppress your immune system, such as azathioprine (Imuran), 6-mercaptopurine (6-MP), or methotrexate.

Changes in body function can occur, such as retaining fluid (with symptoms including shortness of breath, swelling of ankles or feet, and/or sudden weight gain), liver injury (with symptoms including jaundice causing yellow eyes, yellow skin, or dark urine; pain in the upper part of your right abdomen,

fever, and/or extreme fatigue), joint/muscle pains (occasionally resembling lupus) or rashes (including psoriasis-type rashes), and/or nervous system problems (including vision changes, weakness, numbness and tingling, and/or seizures).

Cancers, including lymphoma (a cancer affecting blood cells) and certain skin cancers, are reported in patients on medications that suppress the immune system, including REMICADE. Hepatosplenic T-cell lymphoma, a rare type of cancer with a high rate of death, may have an association with anti-TNF medications like REMICADE, though the disease is more strongly associated with other medications for Crohn's disease and ulcerative colitis such as azathioprine (Imuran) or 6-mercaptopurine (6-MP). The risk appears to be higher in younger men (< 35 years). As many people on REMICADE are (or have been) on azathioprine or 6-MP, the exact role of REMICADE in hepatosplenic T-cell lymphoma is unclear.

IMPORTANT SAFETY INFORMATION:

In deciding to use a medication, the risks of taking the medicine must be weighed against its benefits. Your Northwest Gastroenterology (NWGI) gastroenterologist should discuss these risks and benefits before you decide to start REMICADE.

Before starting REMICADE, you should inform your doctor if you have:

- A history of tuberculosis (TB) or exposure to someone with TB. Even if you have no history of TB or exposure to TB, your NWGI gastroenterologist will likely check you for TB with either a skin test or a blood test (for example, QuantiFERON Gold), as well as a chest x-ray. If you appear to have inactive tuberculosis, you will need to begin anti-TB treatment before you start REMICADE;
- Lived in a region where fungal infections like histoplasmosis (also known as "cave disease" or "Ohio River valley disease")or coccidiodomycosis (aka "valley fever") are common;
- Infections that keep returning, uncontrolled diabetes, or a problem with your immune system;
- Any type of cancer or a risk factor for developing cancer (for example, a strong family history of cancer);
- Heart failure or any serious heart condition;
- Hepatitis B virus (HBV) infection or close personal contact with someone with HBV; or
- Nervous system disorders like multiple sclerosis (MS)or Guillan-Barre syndrome.

Vaccinations: You should not receive live vaccines (e.g., Varicella [chickenpox] vaccine, Zoster [shingles] vaccine, or live polio vaccine) while on REMICADE. The injected flu and pneumonia vaccines can be safely administered while on REMICADE. The nasal spray version of the flu vaccine is a live vaccine and SHOULD NOT be administered while on REMICADE. Please inform your doctor if someone in your household has received a live virus vaccine.

PREGNANCY AND BREASTFEEDING:

Please tell your NWGI gastroenterologist if you are pregnant, planning to become pregnant, or breastfeeding. This will allow you and your gastroenterologist to discuss appropriate measures related

to your disease and medications. DO NOT stop your Crohn's or ulcerative colitis medications, including REMICADE, without telling your gastroenterologist.

MEDICATION INTERACTIONS:

Please tell your NWGI gastroenterologist if you start new prescription or non-prescription medications, including vitamins and herbal supplements, while receiving REMICADE. This is especially important if you start other immune suppressants such as Humira, Cimzia, Simponi, Actemra, Enbrel, Kineret, Orencia, and Rituxan.

MEDICATION ADMINISTRATION:

REMICADE is administered as a single intravenous infusion lasting approximately 2 hours. Infusion times may vary on the number of infusions you have received. Your NWGI gastroenterologist will determine the correct dose and interval of the infusions. Your will see your NWGI gastroenterologist periodically to monitor your progress and response to REMICADE.

If you have any questions, you can call our office at (360) 734-1420 on Monday through Friday from 8 am to 5 pm.

By signing, I indicate that I have read and understand this consent from and agree to receive REMICADE infusions. I have had an opportunity to discuss this treatment with my physician and have had my questions answered.

Patient Signature Date

Patient Printed Name