HUMIRA (Adalimumab) Informed Consent

What is Humira?

HUMIRA is a biologic drug that is used in the treatment of Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondilitis, Crohn’s disease, and Juvenile Idiopathic Arthritis. It was approved for the treatment of moderate to severe plaque Psoriasis in January 2008.

How HUMIRA works:

HUMIRA is a medication called a TNF blocker. It is a fully humanized protein molecule that blocks a chemical substance (Cytokine) in your body called TNF-alpha, which is present in excess amounts in the skin and joints in patients with Psoriasis and Psoriatic Arthritis.

The excess TNF-alpha causes inflammation in your joints and skin. HUMIRA helps reduce these signs and symptoms of disease and may prevent further damage to your joints.

How to use HUMIRA:

HUMIRA is administered by giving you an injection under the skin. A qualified nurse or medical assistant will teach you how to administer HUMIRA before your treatment. For Psoriasis two injections will be given on your first day of treatment; then one injection one week later; then one injection every other week thereafter. HUMIRA is supplied in a 40 mg injector “pen” to ease its administration.

Who should not take HUMIRA?

1. You should not take HUMIRA if you are allergic to HUMIRA or to any of its ingredients (including sodium phosphate, sodium citrate, citric acid, mannitol, and/or polysorbate 80). The needle cover of the pre-filled syringe contains dry natural rubber. Tell your doctor if you have any allergies to rubber or latex.

2. You should not take HUMIRA if you are pregnant, unless discussed between you, your obstetrician, and our staff.
Before starting HUMIRA please inform your doctor if you have had any of the following:

- Any current active infection of any kind
- A history of recurrent infection
- If you or your family members have had tuberculosis (TB), have had an exposure, or have had a positive tuberculosis skin test.
- If you or any family member have had any systemic fungal infection
- If you have had any disease that affected your nervous system, like multiple sclerosis, or if you are experiencing any numbness or tingling.
- If you are scheduled to have major surgery.
- If you are scheduled to have a vaccination of any kind.
- If you have had Hepatitis B or C.

Lab Requirements:  We will do blood tests at intervals when you are taking HUMIRA.

Common side effects of HUMIRA may include:

- Injection site pain.
- Injection site reactions, which may include redness, rash, swelling, itching, or bruising. This is temporary and should resolve within a few days. Cool compresses may help alleviate these symptoms.
- Increased risk of infections or worsening of common infections such as upper respiratory infection or sinus infections.
- Headache, Nausea, or Rash.

Reported serious side effects, although rare but which may occur are:

- Serious infections caused by bacteria, fungi, or viruses.
- Reactivation of tuberculosis (TB).
- Nervous system diseases.
- Malignancies, including lymphoma.
- Lupus-like syndrome.
- Blood problems/dyscrasias.
- Heart problems/congestive heart failure.
- Allergic reactions.
- Reactivation of Hepatitis B.

Pregnancy

HUMIRA is a category B drug. It has not been studied on pregnant or nursing mothers. Please discuss with your doctor if you are planning a pregnancy. Please report immediately to your doctor if you become pregnant while taking HUMIRA.
Special Circumstances

You should not receive live vaccines while using HUMIRA. Please talk to our staff if you need to receive a vaccine while using HUMIRA.

Drug Interactions:

Let your physician know before you start another immunosuppressive agent. Please discuss with our staff all medications (oral, topical, intravenous, injectables, etc) you are currently taking including non-prescription/over-the-counter medication, vitamins, and herbal supplements.

KEEP HUMIRA OUT OF THE REACH OF CHILDREN

STORING HUMIRA.
HUMIRA needs to be kept in a refrigerator (at 2º - 8º C/ 36º - 40º F) and needs to be kept out of direct light.
Do not freeze HUMIRA.
Check the expiration date before using.
HUMIRA must be taken on board when traveling on an airplane.

Disposing of Used Needles, Syringes, and HUMIRA pens.

- Place the used needles, syringes, and injector pens in a Biohazard/sharp container for medical waste, which is puncture proof. These may be obtained at your pharmacy or from MY HUMIRA support. MY HUMIRA also has a disposal service available to you at no charge.
- Do not reuse needles, syringes, injector pens, or alcohol pads. Always keep syringes, HUMIRA pens, injection supplies, and disposal containers out of the reach of children and pets.
- If you choose to dispose of needles and not use MY HUMIRA disposal service, contact your town or city Environmental Waste Department on how to dispose of your Biohazard containers. These laws vary from state to state.

Participation in this therapy;

You are responsible to follow the instructions given to you by the physicians and staff at West Houston Dermatology. Please do not fail to get blood tests as indicated.

You will be scheduled for regular follow-up visit. It is essential that you do not miss your scheduled appointments. Multiple late or missed appointments may result in our discontinuing your therapy.

IF YOU HAVE ANY QUESTIONS OR CONCERNS ABOUT YOUR TREATMENT WITH HUMIRA, IF YOU FEEL YOU ARE EXPERIENCING SIDE EFFECTS, OR IF YOU BEGIN TAKING ANOTHER MEDICATION, PLEASE CALL (281) 558-3376
Chart # ____________

INFORMED CONSENT

My doctor and nurses have discussed alternative treatment options for my skin and joint psoriasis, including other medications such as topical preparations, light treatments, oral, and other injectable therapies.

My doctor and nurses have discussed my treatment with HUMIRA. I understand that I will have lab testing before treatment with HUMIRA, which will include tests for previous exposures to hepatitis, and HIV. I will also be tested for exposure to tuberculosis (Mantoux TB skin test) and may also be requested to have a chest X-ray, if indicated.

I have received adequate information necessary to initiate treatment with HUMIRA. I am voluntarily consenting to take HUMIRA for the treatment of my disease. I agree to give myself the injections as instructed and to comply with all necessary exams and laboratory testing. I can withdraw from the therapy at any time. However, I will contact West Houston Dermatology promptly should I discontinue HUMIRA.

If you have any questions or concerns about treatment with HUMIRA, if you feel you are experiencing side effects, or if you begin taking another medication please call (281) 558-3376

Patient Name (print) ___________________________ Date: ______________

Patient, Parent, or Guardian Signature __________________________________

Witness to Consent: ____________________________ Date: ______________