DIGESTIVE HEALTH ASSOCIATES, P.C.

Consent to Immunosuppressive Therapy with a TNF (tumor necrosis factor) Inhibitor

This document helps us inform you about this procedure. Please read it carefully and address any questions or concerns you may have personally with the doctor prior to signing it.

Dr. Patrick D. Gerstenberger, Dr. Steven R. Christensen, Dr. Stuart B. Saslow, Laura Parker, NP and/or Beth Glotfelty, PA-C are authorized to treat my condition with a TNF inhibitor, such as Remicade® (infliximab), Humira® (adalimumab) or Cimzia® (certolizumab).

ALTERNATIVES:

1. Continuing to try to manage your disease with other medications, including steroids.
2. Surgery.

RISKS: TNF inhibitors are biologic agents that suppress the immune system. While this effect may help Crohn's disease and ulcerative colitis, these drugs may also cause side effects, some of which can be serious. Your gastroenterologist recommends TNF inhibitor therapy only when he believes that the risks of the untreated or inadequately treated disease, or the risks of alternative treatment approaches, are higher than the risks associated with the risks of using these agents. The more common and serious risks include:

1. Injection site reactions
2. Infusion reactions
3. Low white blood cell count
4. Infections, which in rare instances are life-threatening (tuberculosis and other bacterial, viral and fungal infections)
5. Neurologic disease, such as multiple sclerosis or similar “demyelinating disease” (suspected though not proven)
6. Cardiac, pulmonary or liver toxicity
7. Dermatologic reactions
8. Malignancy (lymphoma, nonmelanoma skin cancer, melanoma)
9. Autoimmune disease (development of immune system reaction to the biologic agent, decreasing its effectiveness and potentially leading to other immune-related problems).

Complications may occur even when treatment is properly monitored, but it is important to follow your doctor’s recommendations for scheduled blood tests to monitor your care.

PATIENT CONSENT
I have had sufficient opportunity to discuss my condition and treatment with my physicians and/or their associates, and all of my questions have been answered to my satisfaction. I believe that I have adequate knowledge upon which to base an informed consent to the proposed procedure.

I have read and fully understand this form and I voluntarily authorize and consent to this procedure. I understand that I should not sign this form until all my questions have been answered to my satisfaction and until I understand all the words or terms on this form.

I am aware that the practice of medicine is not an exact science, and I acknowledge that no guarantees have been made to me concerning the results of the procedure. I have been advised that the proposed procedure may not improve my condition and may, in fact, worsen it.

*X*____ *Date:* __________________ *Time:* _____________
Signature of Patient or Authorized Agent

____
Printed Patient Name

PHYSICIAN/PROVIDER DECLARATION
I have explained the contents of this document to the patient and have answered all the patient’s questions, and to the best of my knowledge, I feel the patient has been adequately informed and has consented.

____ *Date:* __________________ *Time:* _____________
PA or NP prescribing treatment (if applicable)
____ *Date:* __________________ *Time:* _____________
Physician prescribing treatment

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