

Informed Consent for Treatment of Persistent Lyme Disease

Note: please initial all sections after reading and understanding each one

There is considerable uncertainty regarding the diagnosis and treatment of Lyme disease. No single diagnosis and treatment program for Lyme disease is universally successful or accepted. Medical opinion is divided and two schools of thought regarding diagnosis and treatment exist. Each of the two schools of thought are described in peer-reviewed, evidence based treatment guidelines. The treatment is neither sanctioned or knowingly prohibited by the local state regulatory agency. Patients must weigh the risks and benefits of treatment in consultation with their doctor.

_____ **My Diagnosis.** I understand that I have been diagnosed as having Lyme disease. The diagnosis of Lyme is primarily a clinical determination made by my doctor based on my exposure to ticks, my report of symptoms and my doctor's observation of signs of the disease, with diagnostic tests playing a supportive role.

Doctors differ in how they diagnose Lyme disease.

Some physicians rely on the narrow surveillance case criteria of the CDC for clinical diagnosis even though the CDC itself cautions against this approach. These physicians may fail to diagnose some patients who actually have Lyme disease and for these patients treatment will either not occur or will be delayed.

Other physicians use broader clinical criteria for diagnosing Lyme disease. These physicians believe it is better to err on the side of treatment because of the serious consequences of failing to treat active Lyme disease. These physicians sometimes use antibiotic responsiveness of a patient to assist in their diagnosis. Since no treatment is risk-free, use of broader clinical criteria to diagnose disease could in some cases expose patients to increased treatment complications.

I understand that it is conceivable that some or all of my current symptoms either may not be due to this illness or they may represent permanent changes in my system. In this case further antibiotic treatment may not be of benefit.

_____ **My Treatment Choices.** The medical community is divided into two groups regarding the best approach for treating persistent Lyme disease. Many physicians follow the treatment guidelines of the Infectious Diseases Society of America (IDSA) that recommend short term treatment only and view the long-term effects of Lyme disease as an autoimmune response or permanent damage that is unaffected by antibiotics.

Other physicians believe that the infection persists, is difficult to eradicate and therefore requires long-term treatment with antibiotics frequently in high and/or combination doses. These physicians follow the guidelines of the International Lyme and Associated Diseases Society (ILADS). Other complementary and alternative modalities like herbal formulas and supplements may be added to the treatment regimen at the discretion of the treating physician but are not part of the presently prescribed ILADS protocols.

_____ **Potential Benefits of Treatment.** Some clinical studies support longer term treatment approaches while others do not. Although most patients improve with continued treatment, some do not.

_____ **Proposed Treatment.** I understand that I will be treated for Lyme disease and other tick borne diseases by Dr. Warren Klausner. My treatment may involve the use of antibiotics, anti-parasitics, anti-arthritics, nutritional supplements, a rehabilitation program and possible other therapies. I understand that some medications which might be employed are used for off-label indications. I understand that some clinical studies support longer term treatment approaches while others do not. I understand that while many patients improve with these protocols, others do not.

_____ **My Required Participation in Treatment.** I understand that much of the diagnostic, management and clinical decisions and conclusions made in my case by Dr. Klausner require my input, cooperation and compliance. I agree to my honest and accurate reporting of all symptoms, willingness to do ongoing reasonable testing as requested and compliance with proper diet and supplement protocols which are designed to make treatments more effective. I realize that I am an active participant in the diagnostic and therapeutic process, the success of which is dependent upon my compliance and I do accept and agree to share responsibility for any and all outcomes.

_____ **Risks of Treatment.** There are potential risks involved in using any treatment, just as there are risks in foregoing any treatment entirely. Some of the problems with antibiotics may include allergic reactions, stomach or bowel upset, yeast infections. Severe allergic reactions may require emergency treatments, while other problems may require suspension of treatment or adjustment of treatment protocols. It is also possible that medications used in the treatment of Lyme and other tick borne disease and their symptoms could result in other problems such as adverse effects on liver, kidneys, gallbladder or other internal organs.

_____ **Factors to consider in my decision.** I understand that no one knows the optimal treatment for symptoms that persist after someone is diagnosed with Lyme disease and has likely been treated with a simple short course of antibiotics. The appropriate treatment may be supportive therapy without the administration of any additional antibiotics. Or appropriate treatment might involve additional antibiotics and if so no one knows for certain exactly how long to give additional antibiotic therapy. By taking antibiotics for longer periods of time I place myself at greater risk for developing side effects. By stopping antibiotic treatment I may place myself at greater risk that a potentially serious infection will progress. I understand that not all patients respond to antibiotic therapy and not all patients respond adequately to complementary and alternative therapies either. There is no currently available diagnostic test that can demonstrate the eradication of Lyme bacteria from my body. Other forms of treatment designed to strengthen my immune system also may be important. Some forms of treatment are only intended to make me more comfortable by relieving my symptoms and do not address any underlying infection.

My decision about continued treatment may depend on a number of factors and the importance of these factors to me. Some of these factors include the severity of my illness and the degree to which it impairs my quality of life; whether or not I have

co-infections, which can complicate treatment; my ability to tolerate the prescribed treatments and the risks of side effects associated with these treatments; whether I have been responsive to antibiotics in the past; whether I relapse or my illness progresses when I stop antibiotics if I have been taking them; my willingness to accept the risk that if left untreated a bacterial infection potentially may get worse.

I realize that the choice of treatment approach to use in treating my condition is mine to make in consultation with my physician. After considering the risks and benefits of different treatment approaches, I have decided:

_____ To treat my Lyme disease and co-infections through a antibiotic and anti-parasitic treatment approach that relies heavily on clinical judgment and may use antibiotics and anti-parasitics until my clinical symptoms resolve. I recognize that this treatment approach does not conform to IDSA guidelines and that insurance companies may not cover the cost of some or all of my treatment.

_____ Only to treat my Lyme disease and co-infections with antibiotics for 30 days, even if I still have symptoms.

_____ Not to pursue antibiotics therapy

_____ To try using complementary and alternative methods (non-pharmaceutical) as an initial therapy, having been informed by Dr. Klausner that they may not be successful.

Insurance coverage and costs.

_____ By initialing here, I confirm that I understand that the treatment to be provided by Dr. Klausner as well as the testing and other services and supplies, including pharmaceuticals, vitamins and supplements which constitute a part of my treatment, may not be covered by my health insurance carrier.

_____ Accordingly, I acknowledge that I will be individually and personally responsible for payment for all services and goods rendered by Dr. Klausner and for all testing and supplies in excess of payments provided by my insurance carrier. I understand that Dr. Klausner has a fee for service practice and that payment in full is required at the time of each appointment.

_____ I understand and represent that the potential costs of my treatment and my responsibility for payment have been fully explained to me to my satisfaction. I acknowledge that Dr. Klausner and his staff have no knowledge with respect to any amounts of payment I may anticipate from my insurance carriers. I understand that the length and scope and total cost of my treatment cannot be determined in advance. My agreement to consent to and commence with treatment is not made in reliance upon prospective or anticipated insurance payments to me.

_____ **To my knowledge I am not allergic to any medications except those listed below:**

Please note what your reaction is to each item you include on the list

I understand the potential benefits and risks of the proposed course of treatment and of alternative courses of treatment, including the risks and benefits of foregoing treatment altogether. I understand the role to be assumed by Dr. Klausner with respect to my care and the need for me to keep him apprised of any other treating physicians and facilities involved in my care. My questions have all been answered in terms I understand.

Patient Signature _____ Date: _____

Print Patient Name _____

Signature if representative of Patient _____

Print Representative Name _____

Relation to Patient _____

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