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Informed Consent for Treatment of Lyme Disease

There is considerable uncertainty regarding the diagnosis and treatment of Lyme disease. No single diagnostic and treatment program from 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 is described in peer-reviewed, evidence-based treatment guidelines. Until we know more, patients must weigh the risks and benefits of treatment in consultation with their doctor.

My Diagnosis. The diagnosis of Lyme disease 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. 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 the 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. This approach may result in a tendency to over diagnose and over treat Lyme disease.

My Treatment Choices. The medical community is divided regarding the best approach for treating persistent Lyme disease. At this time the majority of physicians follow the treatment guidelines of the Infectious Disease Society of America, which recommend short term treatment only and view the long-term effects of Lyme disease as an autoimmune process 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 intravenous, intramuscular, or oral antibiotics, frequently in high and/or combination doses.

Potential Benefits of Treatment. Some clinical studies support longer term treatment approaches, while others do not. The experience in this office is that although most patients improve with continued treatment, some do not.

Risks of Treatment. There are potential risks involved in using any treatment, just as there are in foregoing treatment entirely. Some of the problems with antibiotics may include (a) allergic reactions, which may manifest as rashes, swelling, and difficulty with breathing, (b) stomach or bowel upset, or (c) yeast infections. Severe allergic reactions may require emergency treatments, while other problems may require suspension of treatment, or adjustment of medication. Other problems such as adverse effects on liver, kidneys, gallbladder, or other organs may occur.

Factors to consider in my decision. No one knows the optimal treatment of symptoms that persist after a patient is diagnosed with Lyme disease and treated with a simple short course of antibiotic therapy. The appropriate treatment may be supportive therapy without the administration of any additional antibiotics. Or, the appropriate treatment might be additional antibiotic therapy. If additional antibiotic therapy is warranted, no one knows for certain exactly how long to give the additional therapy. By taking antibiotics for longer periods of time, I place myself at greater risk of developing side effects. By stopping antibiotic treatment, I place myself at a greater risk that a potentially serious infection will progress. Antibiotics are the only form of treatment shown to be effective for Lyme disease, but not all patients respond to antibiotic therapy. There is no currently available diagnostic test that can demonstrate the eradication of the 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 (a) the severity of my illness and degree to which it impairs my quality of life, (b) whether I have co-infections, which can complicate treatment, (c) my ability to tolerate antibiotic treatment and the risk of major and minor side effects associated with the treatment, (d) whether I have been responsive to antibiotics in the past, (e) whether I relapse or my illness progresses when I stop taking antibiotics, and (f) my willingness to accept the risk that, left untreated, a bacterial infection potentially may get worse.

For example, if my illness is severe, significantly affects the quality of my life, and I have been responsive to antibiotic treatment in the past, I may wish to continue my treatment. However, if I am willing to accept the risk that the infection may progress or if I am not responsive to antibiotics, I may wish to terminate treatment. I will ask my doctor if I need any more information to make this decision and am aware that I have the right to obtain a second opinion if I think this would be helpful.

My questions have all been answered in terms I understand, I am aware of the risks involved in antibiotic and in foregoing antibiotic treatment. Based on this information, I have decided: (CHECK ONE)

- To treat my Lyme disease with antibiotics until my clinical symptoms resolve.
- Only treat my Lyme disease with antibiotics for thirty days, even if I still have symptoms.
- Not to pursue antibiotic therapy.

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

I understand the benefits and risks of the proposed course of treatment, and of the alternatives to it, including the risks and benefits of foregoing treatment altogether. My questions have all been answered in terms I understand. All blanks on this document have been filled in as of the time of my signature.

Signature: _____

Date: _____

Print Name: _____

Witness: _____