

## CONSENT to treat Chronic Persistent Lyme Disease

There is considerable uncertainty regarding the diagnosis and treatment of Lyme disease. No single diagnostic 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 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, 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 process or permanent damage that is unaffected by antibiotics.[1] Other physicians believe that the infection persists, is difficult to eradicate, often associated with "co infections" or additional organisms and therefore requires long-term treatment with intravenous, intramuscular, or oral antibiotics, frequently in high and/or combination doses. In fact, there have been questions as to the validity of the aforementioned (IDSA) guidelines, that have been published in the peer reviewed literature [2-4]. Alternative guidelines promoted by the International Lyme and Associated Diseases Society (ILADS) [5] support the concepts that diagnostic technology and criteria for the diagnosis of Lyme disease are often too INSENSITIVE. That the clinical judgement in the appropriate setting as described above, ought to provide the clinician at the point of care with the ability to diagnose and clinically determine the activity of this infectious process. That this approach supports the concepts that this complex may be difficult to treat and may require longer courses of antibiotics, in protocols such as pulsing or cycling. That while doing all we can to "do no harm," the perspective remains that oftentimes quite ill patients would often benefit from these "alternative" approaches to the management of this most complex process [6]

**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, potentially

herbal/complimentary supplements may be warranted. Or, the appropriate treatment might be additional antibiotic therapy, either oral or intravenous. 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 greater risk that a potentially serious infection will progress [7]. 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 [8]. 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 that may be important 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 unresponsive 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 at any time if I think this would be helpful.

**I realize that the choice of treatment approach to use in treating my condition is mine to make in consultation with my physician. After weighting the risks and benefits of the two treatment approaches, I have decided: (CHECK ONE)**

<input type="checkbox"/>	To treat my Lyme disease through a treatment approach that relies heavily on clinical judgment and may use antibiotics either oral or IV, depending upon my doctor's clinical judgment, 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.	<input type="checkbox"/>	Not to pursue antibiotic therapy
<input type="checkbox"/>	Only to treat my Lyme disease with antibiotics for thirty days, even if I still have symptoms.		<p>I may obtain a copy of IDSA guidelines by going to:  <a href="http://www.cdc.gov/ncidod/dvbid/lyme/IDSA_2000.pdf">http://www.cdc.gov/ncidod/dvbid/lyme/IDSA_2000.pdf</a></p> <p>ILADS guidelines by going to:  <a href="http://www.ilads.org/files/ILADS_Guidelines.pdf">http://www.ilads.org/files/ILADS_Guidelines.pdf</a></p>

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:** \_\_\_\_\_

1. Wormser GP, Raj Dattwyler, ED Shapiro, AJ Halperin, AC Steere, MS Klemperer, PJ Krause, JS Bakken, F Strle, G Stanek, L Bockenstedt, D Fish, JS Dumler, and RB Nadelman. The clinical assessment, treatment, and prevention of Lyme disease, Human Granulocytic Anaplasmosis, and Babesiosis: Clinical practice guidelines by the Infectious Diseases Society of America. *Clin Infect Dis.* 2006; 41(1 November): 1089. Available at <http://www.idsociety.org/content.aspx?id=4432#ld>
2. Khan AR, Khan S, Zimmerman V, Baddour LM, and Tleyjeh IM Quality and Strength of Evidence of the Infectious Diseases Society of America Clinical Practice Guidelines CID (15 November) 2010:51
3. Deresinski S Guiding Clinical Care through Evidence-Free Zones CID (15 November) 2010:51 1157-1159
4. Johnson L and Stricker RB The Infectious Diseases Society of America Lyme guidelines: a cautionary tale about development of clinical practice guidelines *Philosophy, Ethics, and Humanities in Medicine* 2010, 5:9 doi:10.1186/1747-5341-5-9
5. The International Lyme and Associated Diseases Society. ILADS Evidence-based guidelines for the management of Lyme disease. *Expert Rev. Anti-infect. Ther.* 2004; 2(1): S1–S13. Available at [w.ilads.org](http://w.ilads.org)
6. Shor, S Retrospective analysis of a cohort of Internationally Case Defined Chronic Fatigue Syndrome patients in a Lyme endemic area *Bulletin of the IACFS/ME.* 2011;18(4):109-123
7. Virginia Governor McDonnell's task force on Lyme disease 2010-2011, position paper published June 30, 2011
8. Cameron DJ Consequences of treatment delay in Lyme disease *Journal of Evaluation in Clinical Practice* 13 (2007) 470–472

## Intravenous Treatment Consent Form

In certain situations, intravenous (IV) medications are preferred or may be used to supplement oral medications. IV treatment is sometimes recommended when there is neurological involvement, heart problems, severe joint inflammation, or inadequate response to oral medications. Because the GI system is bypassed, IV dosing greatly increases the probability of adequate medication blood levels and reduces gastrointestinal symptoms. IV antibiotics also may penetrate the blood brain barrier more effectively.

There are additional risks associated with IV treatment. IV treatment usually involves the installation of an intravenous line in my vein to allow easier IV treatment. PICC lines may result in local infection, or if unchecked, systemic infection. If signs of skin inflammation occur, the line may need to be removed. Rarely, PICC lines break off when they are being removed and may then require surgical removal. There is also a chance that, upon insertion, a nerve near the vein could be damaged. There is a risk of blood clots from PICC line insertion. If a clot forms, the PICC line may be removed and I may be hospitalized for the initiation of anti-coagulation therapy. The risk of clot development is decreased, although not eliminated, by flushing the PICC line twice daily with saline and heparin and by avoiding vigorous repetitive motion activity of the arm in which the PICC line is placed.

The major side effects of ceftriaxone, an intravenous antibiotic often used for treating persistent Lyme disease, include rash (in about 1.7% of all cases), diarrhea (2.7%), changes in liver function (approximately 3%) and gallstones (less than 1%). Ceftriaxone is related to penicillin, and a small percentage of patients with penicillin allergies will have allergic reactions to ceftriaxone (5-8%). Some patients when treated with ceftriaxone develop pain that seems like gallbladder disease. This usually goes away after the medication is stopped. However, some patients using ceftriaxone have had their gallbladders removed. Some doctors believe that this risk can be reduced by taking a medication called Actigall with the ceftriaxone. Other antibiotics commonly used to treat Lyme disease are not known to have gallbladder side effects. Monitoring my blood may help detect the development of any liver or gallbladder problems, but does not guarantee that gallbladder or liver problems will not ensue.

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My questions have all been answered in terms I understand. I am aware of the risks in foregoing IV treatment as well as the potential side effects if I undergo this treatment, and I consent to the use of IV treatment.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Print Name: \_\_\_\_\_

Witness: \_\_\_\_\_

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

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