Study of Lyme disease Immunology and Clinical Events

SLICE is a landmark study sponsored by LymeMD. A collaborative initiative with the Division of Rheumatology at Johns Hopkins, the *SLICE* study is a translational research study that connects the "bedside observations in the clinic" to the research labs of Johns Hopkins. The study examines the impact of Lyme disease on the human immune system and on patient health. We believe that understanding how the immune system responds in Lyme disease is the key to discovering why many patients experience persistent symptoms *even after* antibiotic treatment of their Lyme disease. We must understand the causes of chronic illness associated with Lyme disease *before* we can formulate effective treatments for patients.

Our *SLICE* study uses a powerful prospective study design - for the first time ever in the United States – to understand the patterns of immune response in patients who develop the disabling chronic symptoms of fatigue and pain *after* treatment of their Lyme disease.

Each of us has an immune response designed to control infection. But sometimes, this response creates damage and actually perpetuates symptoms. With Lyme disease, the patient's immune system's 'good' response fights the infection, but there can also be a 'bad' response (autoimmunity) to the invading bacteria of Lyme disease. The goal of our *SLICE* study is to examine both the good and bad responses of the immune system in patients before and after their initial antibiotic treatment. In addition, we will search for associated biomarkers (blood tests that may show a correlation with disease activity or prognosis) that can be used to monitor and guide therapy of patients with Lyme disease.

For the study, we are recruiting 100 patients with acute, untreated Lyme disease who will be treated and followed for two years. Their symptoms will be measured with standardized surveys completed by the patients to record their symptoms and intelligence tests administered by our staff to measure their cognitive function. Samples of their blood, immune cells, DNA, and RNA will also be collected and stored for future research and analysis.

We predict that our *SLICE* study will provide fundamental insights into the relationship of immune pathways, biomarkers and the persistence of symptoms in patients with Lyme disease that may be clues to the cause of persistent symptoms and may serve as the basis for future diagnostic tests.

SLICE holds promise for breakthroughs in the way we understand the chronic impact of Lyme disease and the first steps towards treatments to restore the health of those individuals who desperately need our help. It is an exciting undertaking.