

Dr Richard I. Horowitz, Medical Director

Hudson Valley Healing Arts Center

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To Our Patients:

At the heart of good medicine is meticulous attention to patients' symptoms, medical tests, and medical records. By paying careful attention to your complaints, our staff can ensure that we obtain a proper medical history and provide you with the best care.

Most chronic illnesses are complex, and have causes that are likely interrelated. Patients with chronic symptoms after classical treatment for Lyme disease have multifactorial causes for their illness. I call this syndrome Lyme-MSIDS. MSIDS stands for Multiple Infectious Disease Syndrome, and represents sixteen potential overlapping medical problems contributing to persistent symptoms in the Lyme patients. By identifying all of your symptoms, you can assist our providers in developing a set of differential diagnoses to better plan your treatment. Your symptoms are essential clues for making an accurate diagnosis.

In order to track your progress during treatment for Lyme and other co infections and to provide you with the very best care, we are undertaking a study in which we will ask that you complete a self-report questionnaire that lists a range of symptoms you may be experiencing. Not all the items on this questionnaire are specific to Lyme disease in and of themselves, and many can be found in other illnesses. However, the constellation of symptoms you present with can assist us to reach a decision about whether you are likely suffering from Lyme disease and associated tick-borne disorders.

We are undertaking this research study in order to provide both new and experienced physicians with a screening questionnaire that identifies whether a patient has a high or low probability of having MSIDS-tick-borne illness. Our plan is to compare patients' reported symptoms on the Questionnaire with their blood test results with the goal of learning which symptoms best predict the likelihood of having MSIDS-tick-borne illness.

If you choose to participate in this study, along with completing the Horowitz MSIDS Symptom Questionnaire, our phlebotomist will withdraw a small quantity of blood (venipuncture) during your office visit. This blood sample will be sent to IgeneX Laboratory in CA (for identification of tick-borne disorders via Western Blot), and if you agree, also to Milford Medical Laboratories in CT for a new DNA/PCR test for *B. burgdorferi* and *miyamotoi*.

If you choose to participate in this research study, you might be asked to complete the MSIDS Symptom Questionnaire more than once over the course of your treatment so we can track your progress. Your completed symptom questionnaire(s) and blood test results will become part of your confidential health record maintained at the Center. If you choose to participate in this

research study, the health staff at the HVHAC will discuss the results of both the questionnaire and blood test during your next office visit or during your next scheduled phone consultation.

Any disclosure of our findings about the range of symptoms or blood test results over the course of treatment in our practice for presentation in scientific forums or for publication only will be reported in ways that aggregate results from multiple patients and de-identify you as an individual patient. (In other words, we will never report your questionnaire responses or blood test results in a way that you can be identified as an individual by name, address, geographic region, race, or age). We will need to keep track of patients' gender, diagnosis, and how long they have been ill, in any report of our findings but without identifying individual patients in our reports. Once we match your Questionnaire scores with your blood test results, we will delete your names and use only a CODE for our data analysis and reporting.

Your responses on these questionnaires and blood test results will become part of your confidential medical record and will only be accessible to members of the health staff at the HVHAC and to researchers who have signed a confidentiality agreement never to reveal individual identifiable responses.

Although we are undertaking this study as part of a research project, the most important goal is to use your answers on the questionnaire and your blood test results to assist us in providing both you and subsequent patients with the best care, support, and encouragement as our patients progress through treatment for tick-borne infections.

Although I do encourage you to complete the questionnaire and agree to the blood draw, deciding not to participate in this project or withdrawing from our project once you start to participate, will NOT affect your care or treatment at the HVHAC.

We have included copies of the questionnaire and instructions for completing it in this package so you can see what we are asking you to do.

If you agree to take part in our study on the relationship between your clinical symptoms and blood test results as part of your treatment for Lyme disease and other co infections at the HVHAC, please sign and date this form and return it to the nursing staff. They can make you a copy for your files.

Informed Consent

I hereby agree to take part in a research study on the relationship between my self-reported complaints/symptoms on the Horowitz MSIDS Questionnaire and my blood test results for diagnosis and treatment for Lyme disease and other tick-borne infections at the Hudson Valley Healing Arts Center under the direction of its medical director, Dr Richard I. Horowitz, (845) 229 8977. I understand that I will be asked to complete the MSIDS Symptom Questionnaire (perhaps more than once) during the course of my treatment and to submit to a blood draw (venipuncture) by the Center's phlebotomist. **I understand that I am responsible for any**

charges for my diagnosis and treatment for Lyme-MSIDS at the HVHAC including the blood tests that are part of this research protocol.

Confidentiality: I understand that my responses on these Questionnaires and the blood test results will become part of my medical record. My responses and test results only will be accessible to members of the medical staff and to researchers who sign a confidentiality agreement at the Center for the duration of this study.

Privacy: I understand that any publication of research coming from these Questionnaires and blood draws will de-identify patients so that no single individual's responses will be identifiable by name, address, geographic region, race, or age.

Right to Withdraw: I understand that I can withdraw my agreement to participate in this study at any time without any consequences for my treatment at the Center

Potential Benefits: The potential benefits to participating in this study are that I can receive appropriate care, support, and encouragement for my symptoms and blood test results over the course of my treatment. My results potentially also can assist the treatment of other Lyme disease-MSIDS patients.

Potential Risks: The only potential risks that might arise in completing these Questionnaires or in having the blood draw are that doing so might cause me to feel some concern or some anxiety or some minor pain or discomfort during or after the venipuncture. I understand that should these feelings or discomfort arise, I will share any feelings of anxiety or concern when completing these Questionnaires or minor pain or discomfort when having the blood draw with Dr Richard Horowitz and the medical staff at (845) 229 -8977, so that they can take appropriate action to assist me.

Name (Print) _____ Signature and Date _____

Witness _____