

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: **The Western Connecticut Healthcare Lyme Disease Registry**

INVESTIGATOR: Ramin Ahmadi, MD, MPH

SITE: Department of Medical Education and Research
Danbury Hospital
24 Hospital Avenue
Danbury, CT 06810

**STUDY-RELATED
PHONE NUMBER(S):** (203) 739-8383

Instructions:

Please read this consent form carefully and take your time making a decision about whether to participate. As the researchers discuss this consent form with you, please ask him/her to explain any words or information that you do not understand. The purpose, risks, inconveniences, discomforts, and other important information about the study are listed below. Your decision to participate is voluntary. If you decide to participate, you will be given a signed copy of this form to keep.

Why is this study being done?

The number of people with ongoing symptoms of Lyme disease and those who experience relapse after having been treated for Lyme disease are on the rise. Danbury Hospital recognizes that patients with persistent symptoms historically have not been included in most Lyme research studies even though these patients with later stage symptoms were often the most disabled by the illness.

In order to better understand Lyme disease, this registry has been formed to serve members of the Greater Danbury community suffering from Lyme disease. This Lyme Disease Registry will specifically focus on the development of a comprehensive database to better understand the natural course of the illness and its associated symptoms.

Why am I being asked to take part in this research study?

You are being asked to take part in this study because you are at least 5 years old and have been diagnosed with Lyme disease.

How many people will take part in this study?

There is no limit on the number of people who can participate in the study. The more subjects involved in the study only increases our ability to learn more about the impact of Lyme disease in the community.

What is involved in the study?

If you would like to participate in this Lyme disease registry, you will be asked to provide documentation of your Lyme disease diagnosis from your doctor. After that, you will be asked to sign this consent form and then the following procedures and evaluations will be carried out:

- You will be asked to come to the Danbury Hospital Lyme Registry office for blood draw (about 2 tablespoons). Lyme related tests will be conducted as part of future research studies using the Lyme Registry database.
- Obtain your height, weight, and a skin examination for signs of Lyme disease activity. If rash is present, a picture of the rash will be taken;
- Answer survey questions on the Lyme Registry Subject Intake Form.

This intake survey will last approximately 45 minutes.

Every six months, the Lyme Registry will send you a Lyme Registry Subject Follow-up Form (sent to you via e-mail, fax, or regular mail).

Procedures for storing of extra or left over blood samples:

Your samples will be stored using an identification number that will be unique to you. Your name or other personal information will not be included with any data shared with other investigators. Samples will be stored with the Danbury Hospital Department of Medical Education and Research. Tests will be done on these samples to help in the investigation of Lyme disease.

How long can I expect to be in this study?

The study will continue for an indefinite period of time.

You can choose to stop participating in the study for any reason at any time. However, if you decide to stop participating, we encourage you to tell the researchers. You may be asked if you are willing to complete a final follow-up form.

If you become pregnant during the study, please inform the study investigator.

What are the risks of the study?

1. The risks of drawing blood from your arm may include some temporary discomfort from the needle stick, bruising, or lightheadedness and fainting, and in rare cases, infection at the needle site. Normal precautions will be taken to avoid these difficulties.
2. If you become pregnant while in the study, you may be able to continue your participation. We need to know that you are pregnant, as this information may further the understanding of how pregnancy possibly effects Lyme disease in yourself or your child. Although the blood samples taken in the study are relatively small, if your doctor judges you are not suitable to continue the study (for example, if you already have low blood counts), then your doctor may recommend you discontinue the study.

If you think you have experienced a research-related injury, call **your Primary Care physician or the Principal Investigator Dr. Ramin Ahmadi** at (203) 739-8383.

What are the possible benefits of this study?

There may not be any direct benefits to you. The researchers cannot guarantee that you will benefit from participation in this research.

The information learned from this study may benefit others with Lyme disease in the future. Information gained from this research could lead to better treatment of Lyme disease.

The findings generated from such an approach may ultimately be used to inform the development of more effective diagnostic tests and treatment protocols.

Development of commercial products from research information:

Any blood samples you have donated may result in new products, tests or discoveries. You would not share in any financial benefits from these products, tests or discoveries.

What options are available if I decide not to take part in this research study?

You may choose not to participate in this study without jeopardizing your care. If you do enter the study, you may choose to end your participation in the study at any time and be assured that it will not affect your care or your relationship with your doctor.

Will my insurance provider or I be charged for the costs of any part of this research study?

No. Neither you nor your insurance provider will be charged for anything done only for this research study. This includes blood work related to the study.

What will happen if I am harmed as a result of taking part in this study?

It is important that you report any study-related illness or injury to the research team listed at the top of this form immediately.

If you develop medical complications from participating in this study, the researchers will assist you in obtaining appropriate medical treatment, but this study has no plans to provide financial assistance for additional medical or other costs.

You retain your legal rights during your participation in this research

Can I stop taking part in this research study?

Yes. If you decide to participate and later change your mind, you are free to stop taking part in the research study at any time.

If you decide to stop taking part in this research study, it will not affect your relationship with your doctors or their staff. Your decision will not result in any penalty or loss of benefits to which you are

entitled. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

Your doctor may choose to withdraw you from this research study at any time if the study doctor believes it is best for you to stop being in the study or the sponsor stops the study for any reason.

What Information Will Be Used or Disclosed?

Your health information related to this study that you provided in your questionnaire, including your diagnosis, your medical history, and your symptoms. In addition, blood work related to the study will be used. Investigators will use the results of this study as research only and not include them in your medical record. You will NOT be notified of the results, even if there might be some potential benefit to you.

Who May Use and Disclose the Information?

The following parties are authorized to use and disclose your health information in connection with this research study:

1. The Director of the Lyme Disease Registry, Ramin Ahmadi, MD, MPH and the research and data collection staff of the Lyme Disease Registry
2. A legally constituted review board charged to protect the safety of human subjects in medical research, called the Institutional Review Board of Danbury Hospital.

In addition to this consent form, you will be asked to sign an "Authorization for Use and Disclosure of Protected Health Information." This authorization will give more details about how your information will be used for this research study, and who may see and/or get copies of your information.

Can I be identified personally? No.

Expiration: Your authorization for the use and/or disclosure of your health information will continue indefinitely.

Whom do I call if I have questions or problems?

For questions about the study, please contact the Research Department at (203) 739-6398.

For questions about your rights as a research participant, contact the Danbury Hospital Institutional Review Board at (203) 739-7608.

Do we have your permission to leave a phone message for you at the phone number(s) you have provided? Yes No

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PERSON OBTAINING CONSENT, THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, AND THAT A COPY OF THIS FORM HAS BEEN GIVEN TO YOU.

Printed Name of Participant

Signature of Participant

Date

Signature of Parent/Guardian if Participant is under 18

PERSON OBTAINING CONSENT

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied and that I have discussed the research project with the participant and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered. A copy of the informed consent form was given to the subject.

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date