Lyme and Other Tickborne Diseases Prevention Study

Consent Form (ages 18 and older)

Introduction

The Centers for Disease Control and Prevention (CDC) and the [State] Department of Health invite you to be in a study. We are asking you to be in this study because you live in an area where tickborne diseases occur. Please ask questions if there is anything you do not understand.

What is the purpose of this study?

Through this study, we hope to learn more about how to prevent Lyme disease and other tickborne diseases. Our goal is to better understand how to stop people from getting these diseases.

What do you want me to do if I decide to be in this study?

If you agree to be in this study, we will ask you to take part in a phone-based survey. This survey will take no more than 10-15 minutes. During this survey, we will ask you to answer questions about your property, things you may do to prevent tick bites, and your activities when you spend time in the yard. You may choose not to answer any question, for any reason. From May to October, we will ask that you take part in monthly online surveys. We will send you email reminders to take these surveys. If you do not have access to the internet, we will ask you to take part in phone-based surveys. The surveys will take no more than 5-10 minutes. They will ask if you or your household members have come into contact with ticks. If any household member comes into contact with ticks, we will give them the option to mail in ticks found on their body.

The final monthly survey will be over the phone and will ask if you or any household member has become ill with a tickborne disease and your/their experience with this illness. This survey will take no more than 10-15 minutes to complete. If you or a household member becomes ill with a tickborne disease, we will also ask for permission to access your medical records about this tickborne illness.

What do I need to do regarding [Survey X]?

[Give any instructions regarding Survey X.]

Do I have to be in this study?

You are free to join the study or decide not to join. You may also leave the study at any time, for any reason.

Are there any risks to me if I decide to be in the study?

Some of the survey questions will ask you about your health information related to tickborne illnesses. We will not ask you about any other health information. You may choose to skip any survey question you wish, for any reason. Risks may include accidental loss of your study records and/or non-researchers seeing your study records by accident.

Will the information I give you be kept private?

Your personal information (such as your name, address, and telephone number) and survey answers will be kept private to the extent allowed by law. To protect your privacy, we will keep your record under a code number instead of your name. The researchers will keep a link to you and your coded information. This link will be secured and available only to a limited number of research staff. We will keep your records in locked files and only study staff will be allowed to look at them.

Your personal information in your study record and identifiable data will be kept at [EIP site]. This information will not be shared, except for among/between study researchers. This study is being conducted by [insert Health Department(s)] and the CDC. Your name or other facts that point to you will not appear if we present this study or publish its results.

Are there any benefits from being in this study?

You will get no direct benefit from being a part of this study. Helping to carry out this research has a chance to tell us a lot about how to prevent tickborne diseases. If so, that could be of future benefit to you or someone you know.

Are there any costs from being in this study?

No. You will not need to pay to be in this study. If you answer all study surveys, you will be given \$X in gift cards for your time and effort. You will receive a \$ X gift card for the first survey, a \$Y gift card for each monthly survey, and a \$Z gift card for the final survey. If you decide to answer the study surveys, you will be given a gift card for each survey completed at the end of the study.

Who should I call if I have questions about this study or think I may have gotten sick or been harmed by the study?

If you have questions/concerns about the study or would like to withdraw from the study, please contact [EIP site] at (xxx) xxx-xxxx or Sarah Hook, study coordinator (CDC), at (970) 221-6411. If you think you may have become sick during the study, please contact your doctor. CDC and the [EIP site] cannot offer referrals, treatment, or compensation if you are injured from being in this study.

Who should I call if I have a question about my rights as a research volunteer?

If you have any questions about your rights as a participant in this study, please contact CDC's Human Research Protection Office at 1-800-584-8814 or [EIP site] Human Subjects Contact at (xxx) xxx-xxxx / [State IRB] at (xxx) xxx-xxxx. Leave a message with your name, phone number, and refer to CDC protocol [XXX], someone will call you back.

I have been told about the study. I have been allowed to ask questions. I had all of my questions answered. I would like to participate in the study. By signing this form, I agree to be in the study.

Participant Signature:Date:
