

**CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
WESTERN CONNECTICUT STATE UNIVERSITY**

Study Title: Backyard Integrated Tick Management

Principal Investigator: Neeta Connally, Ph.D., MSPH

Science Building 139

181 White St.

Danbury, CT 06810

Funding Source: Centers for Disease Control and Prevention

Invitation to Participate and Description of Project

You are invited to be in a research study to find out if integrated tick management (ITM) that includes pesticides and rodent bait boxes as methods of tick control, can prevent tick bites and tickborne diseases. You have been asked to take part because you live in an area where tickborne diseases occur. We will enroll up to 115 households from Fairfield County. This study will take place over four years. All participant properties will receive spray treatments and bait boxes. All participants will be asked to complete surveys about tick bites and tickborne diseases at key times throughout the year. You will receive gift cards each year for being in the study. By being in the study, you may help us better understand how to prevent tick bites, Lyme disease, and other tickborne diseases.

To help you decide about being in the research study, you should know about its risks and benefits. This consent form tells you about the study. A member of the research team will also go over the study with you. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

If you agree to be in this study, we will ask you to allow Connecticut Tick Control to apply sprays and place bait boxes on your property. The sprays may be the EPA-registered pesticide beta-cyfluthrin (trade name: Tempo SC Ultra) or water and the bait boxes may contain the commonly used, EPA-registered, pesticide fipronil or no pesticide. Beta-cyfluthrin is a pesticide that is registered for use to control indoor and outdoor pests. All sprays (pesticide or water) will be applied to property edges and on some ornamental vegetation. Fipronil is the active ingredient in treatments used to control fleas and ticks on pets. The small, plastic bait boxes will also contain bait that attracts mice and other small mammals. Mice will enter the boxes through a small opening. If the box contains fipronil, as a mouse moves through a box, it passes under a small wick. The wick will lightly brush the mouse, gently applying traces of low-dose fipronil. The pesticide won't harm the mouse or any other animal that might touch or eat it, but it will kill the ticks on the mouse.

Before applying sprays or placing bait boxes on your property, you will be asked to sign a form that tells Connecticut Tick Control it is OK to access your property. Connecticut Tick Control will spray the edges of your property and ornamental vegetation. The number of bait boxes put on your property will depend on how big your property is and how much forest there is. Connecticut Tick Control will decide how many boxes should be used and where they should be placed. Following application, Connecticut Tick Control will place a yellow placard near the

entrance of your property to indicate the time and date of application. A small white engineer's flag will be placed near the bait boxes to indicate where they are located.

Connecticut Tick Control will spray your property twice during the study. They will apply once in early-May–mid-May in 2018 and again in early-May–mid-May in 2019. They will place bait boxes on your property two times during the three year study. The first round of bait boxes will be placed on your property in August, 2017. These will be removed in October, 2017. The second round of bait boxes will be placed on your property in August, 2018. They will be removed in October, 2018. You will not have to pay for any activities by Connecticut Tick Control. You do not need to be home when sprays are applied or bait boxes are placed or removed from your property. You do not need to do anything regarding the bait boxes placed on your property as part of this study.

You will be called to schedule a time to have sprays applied and bait boxes placed on, or removed from, your property. This call will happen at least one day in advance of the planned visit to your yard. While you are in the study, we ask that you agree to not apply or receive any other tick control treatment to your property. You will be randomly placed in a treatment group (beta-cyfluthrin spray + bait boxes with fipronil or water spray + bait boxes without fipronil). You will not know which treatment you receive. You will be notified which treatment you had at the end of the study.

We will ask you to take part in 6 surveys in the first year, and four surveys in each year in years 2 and 3. You may choose not to answer any survey question, for any reason. In the first year, only, will ask you to take part in a phone-based introductory survey. This first survey should take no more than 15 minutes. During this survey, we will ask you about your household, your property, and activities you spend time doing outside. We will also ask you if you or any household members have had Lyme or any other tickborne disease in the past. We will ask you to take part in brief web-based surveys throughout the study (four times per year) to report any tick encounters. These surveys will take approximately 5–10 minutes and will ask if you or any household member has come into contact with ticks and/or has become ill with a tickborne disease and your/their experience with this illness.

If, while you are in the study, you or any household member comes into contact with ticks, we ask that you remove the tick, take a photo of the tick, and report it on the University of Rhode Island Tick Encounter website ([www.tickencounter.org/tickspotters/submit/ form](http://www.tickencounter.org/tickspotters/submit/form)) by following the instructions on the site.

Ticks will be collected from most of the study properties twice each year. We may ask you to allow us to come to your home and collect ticks from your property. If so, we will explain the process and ask your permission before collecting ticks.

Risks

Some of the survey questions will ask you if you have had any 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. The chemicals in this study used to control

ticks are beta-cyfluthrin and fipronil. Beta-cyfluthrin is a pyrethroid pesticide that is used for both indoor and outdoor pest control. People and pets should stay out of the treated area until it is dry, but then may reenter the treated area. A yellow placard will be placed near the entrance to your property that indicates the day and time the treatment was applied. Fipronil is the active ingredient in many flea and tick control products (e.g. Frontline[®]) used on pets. The amount of fipronil in the bait boxes is 10 times less than that found in products used on pets. The risk of coming into contact with the wick containing this chemical is very low, because it is hidden deep inside the rodent bait box. The box is child-resistant and cannot be opened.

The bait boxes are small and black, and are placed in areas that rodents like. Though you may be aware that they are there, the bait boxes would not be very visible or detract from the outdoor beauty in your yard.

Benefits

Helping to carry out this research has a chance to tell us much about how to prevent tickborne diseases. If so, that could be of future benefit to you or someone you know.

Costs

If you complete all the study surveys, you will be given gift cards each year for your time and effort.

Confidentiality and Privacy

Your personal information (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 study staff will keep a link to you and your coded information. This link will be secured and available only to a limited number of study 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 Western Connecticut State University. This information will not be shared, except for among/between study staff. Your name or other facts that point to you will not appear if we present this study or publish its results.

By signing this form, you allow the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

Treatment Alternatives/Alternatives to Participation

You are free to join the study or decide not to join. The pesticide sprays and bait boxes used for this study are also available through licensed pest control companies. Other substances to kill ticks are also available, as described on the Connecticut State website “Managing Ticks on Your Property” <http://www.caes.state.ct.us>

By signing this consent, you are not giving up any of your rights.

Voluntary Participation and Withdrawal

You are free to choose not to take part in this study. You may also leave the study at any time, for any reason. Between the time of enrollment and the end of the study, if you apply or receive any other tick control treatment you will be withdrawn from the study. If you have questions/concerns about the study or would like to withdraw from the study, please contact Rayda Krell, Backyard Integrated Tick Management Study Coordinator at Western Connecticut State University, 203-837-8835 or Neeta Connally, Principal Investigator at Western Connecticut State University 203-837-8749. If you think you may have become sick during the study, please contact your doctor. Western Connecticut State University and the Centers for Disease Control and Prevention cannot offer compensation if you are injured (or experience a temporary side effect from exposure to beta-cyfluthrin or fipronil) from being in this study.

If you have any questions about your rights as a participant in this study, please contact Western Connecticut State University's Institutional Review Board Chair, Jessica Eckstein, 203-837-8873, or irb@wcsu.edu, leave a message with your name and phone number, and someone will get in touch with you.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand. Please do consider this research and consent form carefully – as long as you feel is necessary – before you make a decision.

Authorization and Permission

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of involvement, possible hazards, and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use (and give out) information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

Name of Subject: _____

Signature: _____

Date: _____

Signature of Person Obtaining Consent

Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Neeta Connally, Ph.D. at 203-837-8749. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact Western Connecticut State University’s Institutional Review Board Chair, Jessica Eckstein, 203-837-8873, or irb@wcsu.edu.