

**LYME AND OTHER TICKBORNE DISEASES  
PREVENTION STUDIES (LTDPS):  
4-Poster Deer Treatment Device Acceptability Survey**

Supporting Statement A for a New Generic Information Collection  
Request

OMB Control No. 0920-1150

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- **Goal of the project:** to evaluate the acceptability of 4-Poster Deer Treatment Devices (4-poster devices) as a communitywide method for reducing ticks important to human health in high Lyme disease incidence (LDI) counties of Connecticut and New York.
- **Intended use of the resulting data:** Results of this survey will inform whether future efforts to evaluate the impact of 4-poster devices on human tick encounters and tickborne disease and to utilize devices as a form of community tick control in high LDI communities are warranted. Additionally, it will identify areas of high acceptance where conducting a future 4-poster device intervention to evaluate impacts on human tick encounters and tickborne disease may be feasible.
- **Methods to be used to collect:** CDC and partners will collect this information using self-administered surveys conducted via internet.
- **Subpopulation to be studied:** Survey invitations will be sent to a random sample of households living in freestanding homes in select high LDI counties in CT and NY (8 counties in CT; 8 counties in NY). High LDI counties are defined as counties with a five-year average (2013-2017) LDI  $\geq 10$  cases per 100,000 persons. In NY, the population will be stratified based on previous experience with 4-poster devices in the community (Suffolk County compared to Hudson Valley counties). One adult over the age of 18 from each residence will be asked to respond to the survey.
- **How data will be analyzed:** This is a voluntary survey and anonymous responses of individuals will be compiled generally and not on an individual basis. We will conduct overall descriptive statistical analyses for survey responses.

## 1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) Division of Vector-Borne Diseases (DVBD) and TickNET partners in Connecticut and New York are requesting approval for a generic information collection (gen-IC) to conduct surveys on the acceptability of 4-Poster Deer Treatment Devices (4-poster devices) as a communitywide method for reducing ticks important to human health in select high Lyme disease incidence (LDI) counties in Connecticut and New York.

Lyme disease is the most common vector-borne disease in the United States, where it is caused by infection with the bacteria *Borrelia burgdorferi* and less commonly, *Borrelia mayonii*. *B. burgdorferi* is transmitted by the *Ixodes scapularis* tick (also known as the blacklegged, or “deer” tick) in the Northeastern, Upper Midwest, and Mid-Atlantic states. CT and NY are considered high LDI states, with average annual incidence rates of 58.7 and 17.3 per 100,000 population, respectively. In addition to the two Lyme disease pathogens, *I. scapularis* ticks also transmit agents of anaplasmosis, babesiosis, ehrlichiosis, Powassan virus disease, and relapsing fever due to *Borrelia miyamotoi* infection.

Heavily forested areas border many communities in the northeastern United States, creating numerous opportunities for non-domestic hosts of human-biting ticks to transport these vectors into the peridomestic environment. One such host is the white-tailed deer (*Odocoileus virginianus*), a primary source of blood for adult blacklegged ticks and lone star ticks. White-tailed deer and blacklegged tick populations have been linked in both abundance and small-scale geographical distribution in the U.S. (Piesman 1979; Anderson and Magnarelli 1980; Shulze 1984, 2001; Wilson 1985, 1990b; Daniels 1993; Stafford 1993; Duffy 1994; Daniels and Fish 1995; Ginsberg and Zhioua 1999; Rand 2003; Ginsberg

2004; Jordan and Schulze 2005; Werden 2014; Kugeler 2015).

The 4-Poster Deer Treatment Device (4-poster device) was designed to topically treat white-tailed deer for *I. scapularis* and *A. americanum* ticks as the deer feed from bait bins. The 4-poster device consists of two vertical, acaricide-impregnated applicator rollers on either side of a central bait bin filled with whole kernel corn. As deer consume the corn, the sides of the head, neck, and ears, where ticks typically feed, are rubbed against the applicators and treated with acaricide (permethrin). Because 4-poster devices target adult ticks prior to female egg laying, significant reductions in the abundance of *I. scapularis* and *A. americanum* nymphs are generally not observed until at least three years post-deployment (Pound 2009a). For this reason, devices are intended to be operated for several consecutive years and must remain in operation during seasons of peak tick activity for continuous control.

Due to the geographical range of white-tailed deer, 4-poster devices have the benefit of providing protection to a much larger area than other environmental controls such as rodent bait boxes or yard applications of acaricides; this means that entire communities can benefit from several well-placed devices. In a high-density deployment of devices, one device can provide protection for approximately 21 hectares of land (Pound 2009b). Treating deer topically with acaricide also directly affects the life cycles of ticks without eliminating the host or spraying large volumes of acaricide into the environment, both of which may be somewhat controversial in some communities

Previous 4-poster interventions have evaluated control of *I. scapularis* and *A. americanum* populations in a variety of settings, with the majority showing moderate to high reductions in the abundance of host-seeking nymphs (Solberg 2003; Carroll. 2002, 2009a, b; Grear 2014; Schulze 2009; Daniels 2009; Miller 2009, Stafford 2009; Pound 2009b). Small-scale initial studies showed a 69-91% overall reduction in the abundance of host-seeking *I. scapularis* nymphs after 2-3-year intervention periods (Carroll 2002; Solberg 2003). On a larger scale, five 4-poster intervention studies conducted concurrently from 1997-2002 as part of the United States Department of Agriculture (USDA) Northeast Area-wide Tick Control Project (NEATCP) found a 71% collective reduction in *I. scapularis* nymphal density following the intervention (Pound 2009b; Brei 2009).

Though indices of entomological risk (e.g. density of nymphs, density of infected nymphs (DIN), and nymphal infection prevalence) are often spatially correlated with tickborne diseases on national, regional, and state scales, they are not considered reliable predictors of human disease at finer scales, such as in endemic communities and neighborhoods (Connally 2006). For example, a recent intervention prospectively measuring the impacts of a single, residential barrier acaricide spray on human-tick encounters found that a reduction in host-seeking nymphal abundance did not correlate with a reduction in human-tick encounters (Hinckley 2016). A follow-up study to the 4-poster intervention at the CT NEATCP site found that the intervention may not have reduced the mean incidence of EM rash in the treatment area or compared to the original control area (Garnett 2011). As such, a large-scale, randomized controlled trial is needed to directly and prospectively assess the ability of a communitywide 4-poster device intervention to reduce human-tick encounters and tickborne disease.

The ability of 4-poster devices to reduce human tick exposure in a community is limited by the willingness of residents to host devices on their property or support placement of devices on other lands in their community. Of the studies mentioned above, few had treatment sites in residential settings, and no data exist on the public's acceptance of 4-poster devices as part of a communitywide tick management system in Lyme disease endemic areas. A cross-sectional survey of adults in high LDI counties of CT and NY will provide insights into the acceptability of 4-poster devices as a method for

community tick control in these regions and reasons for lack of acceptance. Understanding these themes and whether residents would be willing to host devices on their properties or in their communities is the first step in assessing whether 4-poster devices could eventually be integrated as a method of community tick control in these communities. Results from this survey will also identify areas of high acceptance where conducting a future 4-poster device intervention to evaluate impacts on human tick encounters and tickborne disease may be feasible

Section 301 of the Public Health Service (PHS) Act (42 USC 241) authorizes the Secretary of Health and Human Services (HHS) to conduct studies relating to the control and prevention of physical diseases of man, such as TBDs, and to collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities. These regulations are codified in 42 Code of Federal Regulations (CFR) Part A.

## **2. Purpose and Use of Information Collection**

The data collection for which approval is sought will allow DVBD to use survey results to understand the willingness of respondents to have a 4-poster device placed on their properties and in their communities, identify reasons respondents do not support placement of a device in these settings, and evaluate whether acceptance is correlated with respondent or household characteristics, concern for and experience with tickborne diseases, or opinions on community tick control. It will also provide insights into whether future efforts to integrate 4-poster devices into a community tick control program are warranted, and identify areas of high acceptance where conducting a future 4-poster device intervention to evaluate impacts on human tick encounters and tickborne disease may be feasible.

The primary target population for these data collections are adults within a random sample of households among select high LDI counties in CT and NY (Attachment 1). High LDI counties are defined as counties with a five-year average (2013-2017) LD incidence  $\geq 10$  cases per 100,000 persons. One adult aged 18 years or older from each residence will be asked to respond to the survey. The final sample is expected to be representative of the populations with highest tickborne disease risk within these two states, in the absence of non-response.

Information will be collected via a web-based survey (Attachment 4). Participants will be given an option in the survey to watch a video to learn information about 4-poster devices (Attachment 5) rather than read the same information in the survey. An invitation postcard will be used for recruitment (Attachment 2). This postcard will contain a web link and unique access code for completing the survey online. Participants will also be encouraged to contact their state study coordinator to take the survey over the phone, if preferred. The surveys will expire roughly four weeks from the time participants receive the survey invitations. After completion of the survey, participants will be mailed a thank you letter with a \$10 gift card or emailed a thank you notice with a \$10 e-gift card (Attachment 6).

Items of information to be collected include:

- Whether the respondent is 18 years of age or older
- Concerns and experiences related to tickborne diseases in general (e.g., concern about encountering ticks and getting LD, history of tickborne disease diagnosis among household members)
- What entities the respondent feels should be responsible for tick control on private properties (e.g., homeowners, homeowner associations, local government, state government)
- Whether the respondent had ever heard of 4-poster devices prior to taking the survey

- Whether the respondent would support placement of a 4-poster device on their property, other private properties in their neighborhood, or public lands in their community
- Reasons for the respondent not supporting placement of a 4-poster device on their property, other private properties in their neighborhood, or public lands in their community
- Additional demographics and household/property characteristics (gender of the person about whom information will be collected, whether they rent or own their property, approximate property size, number of household members, whether any of the household members are children under the age of 18)
- Whether the address the postcard was sent to is the respondent's mailing address and if not, what the correct mailing address is for the respondent
- Any additional comments the respondent may have about 4-poster devices or community tick control

### **3. Use of Improved Information Technology and Burden Reduction**

Per the Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII, information collection will be conducted using the most current modes of survey data collection, including web-based surveys and applications used on participants' mobile devices (e.g., smart phones and tablets) or computers.

This information collection will be done completely online. The survey will be administered using the Research Electronic Data Capture software (REDCap). Potential participants will be sent a survey invitation (Attachment 2) that includes a survey web link. The beginning of the survey will confirm that the respondent is eligible to take the survey. If not, the respondent will not be allowed to proceed. Potential participants will receive one reminder (Attachment 3) to complete the survey after the initial invitation. The project website (Attachment 7) and EIP site contact information will be provided in case of questions.

These electronic information collection techniques typically reduce burden because participants can submit responses at any time of day that is convenient for them rather than having to schedule phone interviews with project staff.

### **4. Efforts to Identify Duplication and Use of Similar Information**

There are no similar, updated data available; other institutions collecting information on tick control and TBD prevention are not collecting this information as it relates to the acceptability of 4-poster devices and their use as a method of community tick control in high LDI regions. DVBD has verified through RegInfo.gov that there are no other federal collections that duplicate information included in this gen-IC request.

### **5. Impact on Small Businesses and Other Small Entities**

This information collection request will survey individual members of the public and will have no impact on small business or other small entities.

### **6. Consequences of Collecting the Information Less Frequently**

This is a one-time information collection. The timing of conducting this survey in late winter and early spring months is important due to the seasonal nature of tickborne diseases.

## **7. Special Circumstances Relating to Guidelines of 5 CFR 1320.5**

This request fully complies with the regulation 5 CFR 1320.5.

## **8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agencies**

A. A 60-Day Federal Register Notice for the generic ICR was published in the Federal Register on June 8, 2016, Vol. 81, No. 110, pg. 36919. One non-substantive public comment was received. A standardized response was sent.

B. The following agencies and organizations outside of CDC have been consulted on the need for data collection with the audiences, and for the purposes, described in this gen-IC:

### **TickNET investigators**

#### ***Connecticut Emerging Infections Program (CT EIP)***

##### ***Yale School of Public Health***

Linda Niccolai, Director of Yale EIP

James Meek, Associate Director of Yale EIP

Sara Niesobecki, TickNET Coordinator

AmberJean Hansen, TickNET Research Assistant

#### ***Western Connecticut State University (WCSU)***

Neeta Connally, Medical Entomologist

#### ***Connecticut State Department of Public Health (CT DPH)***

Jocelyn Mullins, State Public Health Veterinarian

#### ***New York State Department of Health Emerging Infections Program (NYS EIP)***

##### ***New York State Department of Health (NYSDOH)***

Bryon Backenson, Director, Vector-borne Disease Unit

Jennifer White, Deputy Director, Vector-borne Disease Unit

Adam Rowe, Research Scientist

Alison Kaufman, Program Research Specialist

Kristen Howard, Graduate Student Assistant

#### ***Fordham University***

Vanessa Vinci, Research Scientist

## **9. Explanation of Any Payment or Gift to Respondents**

Participants will be reimbursed \$10 in the form of gift cards to a local store or as e-gift cards as compensation for the time necessary to complete the survey. Participants may choose to not answer

questions and will still receive reimbursement for their time and effort. If participants complete the first eligibility questions but are ineligible (i.e., under the age of 18), they will not continue with the survey or receive gift cards as compensation for their time.

## **10. Protection of the Privacy and Confidentiality of Information Provided by Respondents**

NCEZID's Information Systems Security Officer reviewed this submission and determined that the Privacy Act does apply. Not all of the projects submitted as Gen-ICs under this generic will collect personally identifiable information, but for those that do, the applicable Privacy Act System of Records Notice is 09-20-0136, Epidemiologic Studies and Surveillance of Disease Problems.

All DVBD staff receive appropriate annual privacy and confidentiality training.

Data will be collected and stored in an electronic database on a secure partition of the network with limited user access. All data will be kept private to the extent allowed by local, state, and federal law.

Participation in formative research information collection activities is strictly voluntary. The project (protocol #7262) has received a determination from the CDC Human Research Protection Office (HRPO) and is considered exempt under 45 CFR 46.104(d)(2ii) as of January 21, 2020.

### Information in Identifiable Form

Responsibility for maintaining confidentiality regarding participant information and survey data lies within the respective state site. On a site-specific spreadsheet (not stored in the REDCap database or on the CDC server), each survey access code will be linked to the mailing addresses. All potential participants will be assigned a coded study ID; this is the only ID that will be used in REDCap. Only the state sites will have links to the identifiable data; CDC will receive and store only coded study data. The study data will be stored in separate, secured REDCap databases for each site. Data will be on a secure partition of the Yale University network maintained by Yale's REDCap administrators with limited user access. All data will be kept confidential to the extent allowed by local, state, and federal law. To maintain confidentiality, all data, forms, reports, and other records will be identified by the study ID number only. All computer entry and networking programs will utilize only coded numbers. Study documentation will be maintained according to the respective EIP's IRB file management and retention policy. Links to personally identifiable information will be destroyed following the study, according to the respective EIP's IRB policy. For example, some participating IRBs may require links to be preserved for a certain time period after study completion.

As a CDC-funded research activity involving the collection of identifiable (including coded) sensitive information, as defined in section 301(d) of the Public Health Service (PHS) Act, this study is covered by a Certificate of Confidentiality. Therefore, CDC and any of its collaborators, contractors, grantees, or investigators that receive such information from this study are prohibited from:

- Disclosing or providing, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information about the individual that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information pertains; or
- Disclosing or providing to any other person not connected with the research the name of such an individual or any such information about such an individual that was created or compiled for purposes of the research.



Disclosure is permitted only when:

- Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
- Necessary for the medical treatment of the individual to whom the information pertains and made with the consent of such individual;
- Made with the consent of the individual to whom the information pertains; or
- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

CDC and its collaborators and contractors conducting this research have established, and will maintain, effective procedures to ensure that this research complies with the above requirements.

CDC will ensure:

- 1) that any investigator or institution not funded by CDC who receives a copy of identifiable (including coded) information protected by this Certificate, understands that it is also subject to the requirements of subsection 301(d) of the PHS Act; and
- 2) that any sub-recipient that receives CDC funds to carry out part of this research involving a copy of identifiable (including coded) information protected by a Certificate understands that it is subject to subsection 301(d) of the PHS Act.

All study staff have received training on the importance of protecting the confidentiality of human research subjects and of personal information acquired. Survey respondents will be informed that their information will be held in strict confidence.

Participants may voluntarily withdraw from this study for any reason at any time. If participants wish to withdraw after taking the survey, they can contact their state study coordinator using the information provided on their survey invitation, and their survey responses will not be used for any purpose and will be destroyed.

Only partner sites will have access to personally identifiable information (PII). The personally identifiable information used in this study includes name and addresses purchased and extracted from a commercial marketing database called Marketing Systems Group (MSG).

## **11. Institutional Review Board (IRB) and Justification for Sensitive Questions**

### Institutional Review Board

The project (protocol #7262) has received a determination from the CDC Human Research Protection Office (HRPO) and is considered exempt under 45 CFR 46.104(d)(2ii) as of January 21, 2020 (Attachment 9).

### Justification for Sensitive Questions

No sensitive questions are included in this information collection request.

## **12. Estimates of Annualized Burden hours and costs:**

In this study, participants will complete one web-based survey, which also doubles as the screener (Attachment 4). Attachment 4 will show the OMB control number and burden statement on the first

page. The survey will take approximately 5-10 minutes to complete. For purposes of estimating respondent burden, we used 10 minutes as the average burden per response. We aim to enroll up to 1500 participants or approximately 500 in Connecticut and 1000 in New York (to allow for comparisons to be made between the county with previous exposure to 4-poster devices and the counties without). The estimated number of annualized burden hours is 300 hours. The survey will contain a response limit of 500 completed responses for CT and 1000 completed responses (500 completed responses in each strata) for NY.

Estimated Annualized Burden to Respondents

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Adults of households in select high LDI counties in Connecticut and New York	4-Poster Deer Treatment Device Acceptability Survey	1500	1	10/60	250
	4-Poster Deer Treatment Device Acceptability Survey – Screen out	3000	1	1/60	50
<b>Total</b>					<b>300</b>

Estimated Annualized Burden Costs to Respondents.

The average annual cost burden cost is estimated to be \$7,494.00. The hourly wage estimate is based on the Bureau of Labor Statistics May 2018 National Occupational Employment and Wage Estimates ([http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)) for “All Occupations.”

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Adults of households in select high LDI counties in Connecticut and New York	4-Poster Deer Treatment Device Acceptability Survey	250	\$24.98	\$6,245.00
	4-Poster Deer Treatment Device Acceptability Survey – Screen out	50	\$24.98	\$1,249.00
<b>Total</b>				<b>\$7,494.00</b>

**13. Estimates of Other Total Annual Cost Burden to Respondents and Record keepers**

There are no costs to respondents other than their time to participate.

**14. Annualized Costs to the Federal Government**

Governmental Costs are broken down in the following table.

		<b>Total (\$)</b>
<b>Federal Government Personnel Costs</b>	CDC Project Officer (GS-14 at 0.1 FTE)	\$11,214
	CDC Data Manager (GS-9, 0.25 FTE)	\$13,757
Subtotal, Federal Direct Costs		\$24,971
<b>Cooperative Agreement</b>	Cooperative agreement for implementation and information management	\$50,000
<b>Total Annualized Cost to Government</b>		\$74,971

**15. Explanation for Program Changes or Adjustments**

This is a new information collection request, therefore program changes and adjustments do not apply at this time.

**16. Plans for Tabulation and Publication and Project Time Schedule**

An estimated project time schedule for this gen-IC is outlined below.

<b>A.16 - 1 Project Time Schedule</b>	
<b>Activity</b>	<b>Time Schedule</b>
Survey administered	1-2 months after OMB approval of Gen-IC
Data cleaning and validation	4-7 months after OMB approval of Gen-IC
Analyses	7-12 months after OMB approval of Gen-IC

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

The OMB Expiration Date will be displayed.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.

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## **Attachments**

1. Recruitment areas (high-risk counties in CT and NY)
2. Survey invitation postcard
3. Survey reminder postcard
4. Survey
5. Survey video
6. Thank You letter
7. CDC study website
8. Study protocol
9. Human subjects determination