Backyard Integrated Tick Management Project

Request for OMB approval of an Existing Collection in Use without an OMB Control Number

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Supporting Statement A

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Table of Contents

- **Goal of the study:** To (i) evaluate the effectiveness of specific tick control methods used on single versus multiple adjacent properties to suppress host-seeking ticks infected with Lyme disease spirochetes and to reduce human tick bites, and (ii) to better understand human landscape use patterns and tick exposure locations.
- **Intended use of the resulting data:** Provide suggestions for improving tick/pathogen control methods used in the environment.
- **Methods to be used to collect:** The study will utilize a single-blinded, placebo-controlled design.
- **The subpopulation to be studied:** The study population will consist of all persons (adults and children) living in a freestanding home with tick habitat (i.e., brushy or wooded area on property) in the study catchment area towns of CT and RI.
- **How data will be analyzed:** Odds ratios for human tick bites; Parametric or non-parametric statistical tests to compare the abundance of ticks infected with Lyme disease spirochetes on *treated vs. untreated properties*

Clearance for an Existing Collection in Use without an OMB Control Number is requested for a period of 3 years.

When initially reviewed for PRA applicability, this study was deemed PRA not applicable. For that reason, the study started (i.e., funding was awarded to Western Connecticut State University) in September, 2016. However, after being re-evaluated, it was determined that PRA was applicable. At that point, this ICR was developed to bring the study into compliance.

1. Circumstances Making the Collection of Information Necessary

The collection of information is conducted by Western Connecticut State University (WCSU), and its subcontractor, the University of Rhode Island (URI), as part of a Cooperative Agreement with the Centers for Disease Control and Prevention (CDC) (1U01CK0004912-01). The Cooperative Agreement was established based on WCSU competing successfully for CDC RFA-CK-16-002 (Spatially Scalable Integrated Tick Vector/Rodent Reservoir Management to Reduce Human Risk of Exposure to *Ixodes scapularis* Ticks Infected with Lyme Disease Spirochetes).

The combined number of confirmed and probable Lyme disease cases have exceeded 30,000 in all years since 2008, and recent estimates suggest that the true number of Lyme disease cases may be 10-fold higher. There is no Lyme disease vaccine for use in humans and prevention of infection is therefore completely reliant on personal protective measures (avoiding tick habitat, use of repellent, tick checks or prompt tick removal, etc.) and methods to suppress vector ticks in the environment.

The primary goal of this project is to evaluate the effectiveness of specific tick/pathogen control methods used on single versus multiple adjacent properties on the risk of human exposure to ticks. The secondary goal is to better understand human landscape use patterns and tick exposure locations. The project was initiated in direct response to knowledge gaps, identified by CDC Subject Matter Experts (SMEs), for the use of integrated tick vector/rodent reservoir management to reduce human risk of exposure to *Ixodes scapularis* ticks, the sole vector of Lyme disease in the Northeast. These subject

areas and knowledge gaps were addressed in two recently published review papers authored by CDC SMEs:

- **Eisen, L.**, and R.J. Eisen. 2016. Critical evaluation of the linkage between tick-based risk measures to the occurrence of Lyme disease cases. Journal of Medical Entomology 53: 1050-1062.
- **Eisen, L.**, and **M.C. Dolan**. 2016. Evidence for personal protective measures to reduce human contact with blacklegged ticks and for environmentally based control methods to suppress host-seeking blacklegged ticks and reduce infection with Lyme disease spirochetes in tick vectors and rodent reservoirs. Journal of Medical Entomology 53: 1063-1092.

Section 301 of the Public Health Service (PHS) Act (42 USC 241) (Attachment A) 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 Lyme disease, and 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

Information is collected, under protocols approved by the IRBs at WCSU and URI, from inhabitants of residential properties to (i) compare the effectiveness of an integrated tick management approach at single-treated residential properties vs. contiguously-treated residential properties to reduce human tick bites and (ii) increase the understanding of where people encounter ticks, both near their homes and in other outdoor settings.

Another potential positive outcome of the information collection is more effective targeting of tick control efforts to high risk areas, minimizing pesticide use. Not collecting the information would lead to inadequate evaluation of the implemented integrated tick management program (solely focusing on host-seeking ticks collected from the vegetation) as well as the unacceptable status quo for detailed knowledge of where people encounter ticks within their residential properties and on the residential properties versus elsewhere.

Information will be collected by WCSU and URI researchers from inhabitants (adults and children) of participating residential properties (freestanding homes with tick habitat on the property) located in Connecticut and Rhode Island. Consenting participants will complete one introductory survey by telephone, projected to last no more than 15 minutes (Attachment E). In May–August of Years 1–4, participants will also complete an emailed (SurveyMonkey link) monthly tick encounter survey about the number of ticks found on each member of the household and each household member's tick-borne disease status, projected to take no more than 10 minutes per month to complete (Attachment F). An end-of-season survey will also be administered in March/April each year, projected to take no more than 10 minutes to complete (Attachment H).

In addition, participants will be asked to record location of daily activity on behalf of themselves and household members each day over the first week of June in a single year via emailed daily surveys,

projected to take 70 minutes over the week of participation (Attachment G). Lastly, an end-of-study survey will be administered in September 2020, projected to take no more than 15 minutes (Attachment I). In total, we expect approximately 2 hours or less of total time spent on surveys by consented participants in each year of the study. All survey instruments have been approved by the IRBs at WCSU and URI.

Because this study is scheduled to last four years, an extension ICR will be submitted for OMB review in 2020.

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.

Potential participants may be excluded based on a lack of email address since use of email is critical for the electronic information collection techniques. In addition, 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

CDC SMEs maintain regular contact with other federal agencies that fund research on Lyme disease. No other federal agency supports the applied type of research being conducted in this project. CDC is not aware of the availability of any similar information.

5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently

Collecting information less frequently would lead to reduced data quality due to recall issues.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This information collection request requires respondents to report information more often than quarterly during defined periods of the year (i.e., the peak May-August tick season). Part of the study involves understanding how people use specific habitats, with variable perceived risk of encountering ticks, on their own properties on a daily basis during the peak tick activity period. For accurate recall, this information needs to be documented daily during the relevant time period.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60 day Federal Register Notice was published on May 30, 2017, Vol. 82, No. 102, pp. 24707-24709. Three non-substantive public comments were received (Attachments B1-B3). A standard response was sent to the one comment with a return address.

B. No consultations outside of CDC occurred. The Cooperative Agreement was established based on WCSU competing successfully for CDC RFA-CK-16-002 (Spatially Scalable Integrated Tick Vector/Rodent Reservoir Management to Reduce Human Risk of Exposure to *Ixodes scapularis* Ticks Infected with Lyme Disease Spirochetes).

9. Explanation of Any Payment or Gift to Respondents

Participants will receive $45 in Target gift cards as a token of appreciation for the time taken to complete the study surveys for each year of participation in the study. For the proposed information collection, respondents will be recruited for specific characteristics, including living in certain areas and with certain yard attributes. The more specific the target population, the more difficult it is to recruit eligible respondents. Remuneration for participants' time helps to attract a greater number of potential respondents and also will help retain participants over the course of the multi-year project.

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

This information collection request has been reviewed by CDC's National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)'s human subjects advisor. NCEZID has determined that the Privacy Act does not apply to this information collection request.

There are no plans for CDC to receive any individual-level human data pertaining to this study. Because CDC will not interact or intervene with subjects, and because CDC will not obtain identifiable private information, CDC's role in this study does not constitute engagement in the conduct of human subjects research. For that reason, the Privacy Act is not applicable.

Protection of privacy and confidentiality of information provided by respondents to the primary information collection entities (WCSU and URI) is outlined in the approved WCSU and URI IRB protocols (Attachments K and L): "Data will be collected and stored in an electronic database on secure computers with limited user access. All forms and files will be kept [private] to the extent allowed by local, state, and federal law. All data will be coded by study ID number with the ID number linked to the individual participant. Only WCSU and URI investigators will have links to the identifiable data. Any data that may be shared with CDC will be de-identified prior to sharing. To maintain [privacy], all data, forms, reports, and other records will be identified by the study ID number only. After the introductory survey is completed, all computer entry and surveys will utilize only Study ID numbers. Study documentation (e.g., consent forms, hardcopy surveys, etc.) will be maintained according to WCSU's IRB file management and retention policy. Links to personally identifiable information will be destroyed following the study, once all necessary communication with study participants has been completed. Data management and storage related to recruitment, participation, and study organization will be maintained at WCSU and URI. Responsibility for maintaining [privacy] with regards to participant information,

treatment group, and survey data lies with the PIs at WCSU and URI. Only coded data without direct personal identifiers will be shared with CDC for additional data analysis. The study data collected during phone interviews will be maintained at WCSU and URI in a secured MS Access database on a password protected computer in a locked office space. Copies of electronic and paper files will be kept at WCSU in locked filed cabinets within locked office spaces. All participant tracking and follow-up (phone calls, emails, mailings, etc.) will be completed at WCSU and URI."

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

Institutional Review Board

The Backyard Integrated Tick Management study received the determination on 1/25/2017 of: CDC is not engaged in the conduct of human subjects research per 2008 OHRP engagement guidance. CDC IRB review is not required (Attachment J). Investigator has provided documentation of appropriate local review (012517AH-a). The rationale was as follows: "The above-referenced study has been reviewed and approved by an appropriately constituted IRB, in accordance with the requirements of 45 CFR 46. CDC's role in this study is limited to laboratory testing of ticks collected on the outdoor property of consenting households. There are no plans for CDC to receive any individual-level human data pertaining to this study. Because CDC will not interact or intervene with subjects, and because CDC will not obtain identifiable private information, CDC's role in this study does not constitute engagement in the conduct of human subjects research."

The study has been approved by the IRBs at WCSU and URI (Attachments K and L).

Justification for Sensitive Questions

No sensitive questions are anticipated for the topics planned in this information collection request. The possibility exists that some respondents nevertheless may find certain questions from the surveys to be sensitive in nature. However, questions covering such topics as activity locations, tick bites, and history of tick-borne disease are typical components of medical examinations. These questions are necessary in order to assess the efficacy of the integrated tick management intervention being tested as well as to identify potential risk factors for exposure to ticks.

During the consent process, subjects will be told that they may choose to skip any question they wish, for any reason. They will also be told that they may terminate participation at any time. If a subject asks to be withdrawn from the study, the link between the subject's name and the study data will be destroyed.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

The estimates of burden hours are based on knowledge of similar studies. The maximum estimated burden hours are 1,473 hours over the full study in Years 1-4. The burden hours will differ across study years, with the greatest number of burden hours in Year 1 (779 hours) and smaller number of burden

hours in Year 2 (212 hours), Year 3 (212 hours) and Year 4 (270 hours). There is no cost to respondents other than their time.

The estimated number of annualized burden hours is 557. This represents the average number of burden hours in the four years of the study. For example, the eligibility survey will be completed a total of 500 times, an average of 125 times/year. The estimate is broken out in the table below.

Initial surveys will include an eligibility survey and the consent form to recruit study participants. Consented participants will complete one introductory survey by telephone, projected to last no more than 15 minutes. In May–August of Years 1–4, participants will also complete an emailed monthly tick encounter survey about the number of ticks found on each member of the household and each household member's tick-borne disease status, projected to take no more than 10 minutes per month to complete.

An end-of-season survey will also be administered in March/April each year, projected to take no more than 10 minutes to complete. In addition, participants will be asked to record location of daily activity on behalf of themselves and household members each day over the first week of June in a single year via emailed daily surveys, projected to take 70 minutes over the week of participation.

Lastly, an end-of-study survey will be administered in September 2020, projected to take no more than 15 minutes. In total, we expect approximately 2 hours or less of total time spent on surveys by consented participants in each year of the study.

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Households or Individuals	Eligibility Survey	125	1	15/60	32
	Introductory Survey (including Consent Form)	58	1	30/60	29
	Monthly Surveys	230	4	10/60	154
	Daily Surveys	230	7	10/60	269
	Annual End of Year Survey	230	1	15/60	58
	Final Survey	58	1	15/60	15
Total					**557**

B. Estimated Annualized Burden Costs

The hourly wage estimate is based on the Bureau of Labor Statistics May 2016 National Occupational Employment and Wage Estimates (http://www.bls.gov/oes/current/oes_nat.htm). The burden costs will differ across study years, with the greatest burden costs in Year 1 ($18,586.94) and smaller burden costs in Year 2 ($4,815), Year 3 ($4,815) and Year 4 ($6,131).

The estimated annualized burden cost is $13,290.02.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Households or	Eligibility Survey	32	$23.86	$763.52

Individuals	Introductory Survey (including Consent Form)	29	$23.86	$691.94
	Monthly Surveys	154	$23.86	$3,674.44
	Daily Surveys	269	$23.86	$6,418.34
	Annual Surveys	58	$23.86	$1,383.88
	Final survey	15	$23.86	$357.90
Total				$13,290.02

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

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

14. Annualized Cost to the Government

The project is funded via a Cooperative Agreement from CDC to WCSU (Projected cost for full 4-year project of $1,600,000). Three CDC Subject Matter Experts (Dr. Alison Hinckley, Dr. Lars Eisen, and Dr. Rebecca Eisen) assist with scientific oversight of the project and regulatory compliance (Projected total of 400 hours for full 4-year project for a total cost of $26,000). CDC travel (site visits) also is expected at a total of $7,500 over the full 4-year project period.

The annualized cost to the government is estimated to be $408,375.

Federal Government	CDC Subject Matter Experts: Projected total of 400 hours for full 4-year project ($65 per hour)	$26,000
Personnel and Travel Costs	CDC Travel (4 trips)	$7,500
Subtotal, Federal Direct Costs		$33,500
Cooperative Agreement	Projected cost for full 4-year project	$1,600,000
Total Cost to Government		$1,633,500
Annualized Cost to the Government		$408,375

15. Explanation for Program Changes or Adjustments

This is a new information collection request for an existing collection in use without an OMB control number.

16. Plans for Tabulation and Publication and Project Time Schedule

The responsibility for data tabulation and publication, as well as the project timeline, resides with WCSU. CDC SMEs will participate as appropriate in those activities and monitor project progress. Projected timelines for key activities in this multi-year study are outlined below.

Project Time Schedule	
Activity	**Time Schedule**
Recruitment of study participants	Year 1
Intervention implemented	Years 1-3
Study surveys administered	Years 1-4
Data cleaning and validation	Years 1-4
Data analyses and Publication	Years 3-4

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

Because this project is being designed and carried out by WCSU, instruments were finalized and IRB-approved before the burden statement was included. Adding the burden statement and OMB control number after-the-fact would require an IRB amendment and unnecessarily delay the study.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

A. Authorizing Legislation
B. 60-Day FRN
    1. Public comment
    2. Public comment
    3. Public comment
C. Eligibility survey
D. Consent form
E. Introductory survey
F. Monthly survey
G. Daily survey
H. Annual survey
I. Final survey
J. CDC IRB
K. WCSU IRB
L. URI IRB
M. Recruitment postcard
N. Recruitment door hanger for RI
O. Recruitment door hanger for CT