

Survey of Pet Owners Encountering Ticks (PETs) in Lyme Disease Endemic Areas

Supporting Statement A for a New Generic Information Collection Request

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- **Goal of the study:** To characterize human-pet interactions and human and pet behaviors that increase the risk of pet owners encountering ticks in Lyme disease endemic areas.
- **Intended use of the resulting data:** Findings will be used to target promotion of prevention methods for pet owners that could yield substantial reductions in TBD incidence and to prioritize which pet characteristics or pet-human interaction behaviors should be evaluated in prospective cohort studies. With the increasing rate of pet ownership in the U.S. and the increasing rates of human tickborne disease, the ultimate goal of our efforts is to identify modifiable behaviors of pet owners that can reduce tick encounters.
- **Methods to be used to collect:** CDC and Emerging Infections Program (EIP) partners will collect this information using voluntary, self-administered, web-based surveys.
- **Subpopulation to be studied:** The primary target population for these data collections is pet owners 18 years of age or older who have pets that spend time both indoors and outdoors and live in Lyme disease endemic areas of Maryland.
- **How data will be analyzed:** We will conduct descriptive and regression statistical analyses for survey responses and identify whether certain behaviors of pet owners and/or their pets are associated with increased risk for human-tick encounters, which may be used in future evaluations.

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) Division of Vector-Borne Diseases (DVBD) and the Emerging Infections Program (EIP) in Maryland are requesting approval for a generic information collection (gen-IC) to conduct formative research to generate hypotheses regarding pet owners' or pet behaviors that may increase the risk of human-tick encounters in Lyme endemic areas of Maryland.

In the mid-Atlantic region of the U.S., there are several ticks of public health importance: *Ixodes scapularis* (the black-legged tick), *Amblyomma americanum* (the lone star tick), and *Dermacentor variabilis* (the American dog tick).

I. scapularis ticks can transmit pathogens that cause Lyme disease (LD), anaplasmosis, babesiosis, deer tick virus, Powassan virus, and disease caused by *Borrelia miyamotoi*. Lyme disease, caused by infection with the bacteria *Borrelia burgdorferi*, is the most common vector-borne disease in the United States. In 2014, the incidence of LD in Maryland was 16.0/100,000 per population. LD is most often characterized in early illness by an erythema migrans (EM) rash. Without antibiotic treatment, the infection disseminates, and patients can develop multiple EM rashes, and/or overt rheumatologic, cardiac, or neurologic symptoms. Anaplasmosis occurs after infection with the bacteria *Anaplasma phagocytophilum* and is clinically characterized by a range of symptoms from mild febrile illness to severe disease complicated by organ failure. Babesiosis occurs following infection with parasites of the *Babesia* genus, most often *B. microti*, and clinical symptoms range from silent infection to fulminant disease resulting in death. The severity of illness due to this disease is known to be influenced by several factors, including advanced age, immunodeficiency, splenic function, and coinfection.

A. americanum can transmit the agents that cause ehrlichiosis (*Ehrlichia chafeensis* in humans and *E. canis* in dogs), and *D. variabilis* can transmit the agents that cause tularemia and Rocky Mountain spotted fever.

Contact with pets is increasingly being recognized as a factor that increases human-tick encounters and thereby increases the risk of Lyme and other tickborne diseases in humans. Pets may bring ticks onto the property and even into the home, including on furniture such as sofas and beds. In addition, pet owners may engage in activities with their pets (for instance, hiking) that take both themselves and their pets into tick habitat, increasing the risk of tick encounters for both the pet and the human. A recent publication presented the largest analysis to date exploring the association between pet ownership and human tick outcomes (Jones et al, 2017, *Zoonoses and Public Health*). In that analysis, the authors demonstrated that pet ownership, of cats or dogs or both, resulted in a greater likelihood of household members encountering ticks (both crawling and attached). Further, finding ticks on pets was associated with increased risk of household members encountering ticks. However, there are no data from this study or other studies regarding the specific behaviors and human-pet interactions that result in increased tick encounters for pet owners. Thus, it is important to design studies specifically to explore the association between pet ownership and tick encounters and tickborne disease.

This proposal is for formative research using a cross-sectional study design with a one-time, web-based survey. We will collect information on tick encounters among pet owners and their pets, human and pet behaviors, human-pet interactions, and use of tick control. This study serves to gain experience with the data collection instrument and provide insight into the logistics that will be required to implement future, prospective studies. Ultimately, we intend to implement a prospective study in the future to collect detailed, individual level data. This future prospective study will allow us to better elucidate the role of pets in increasing human risk of encountering ticks. With the increasing rate of pet ownership in the U.S. and the increasing rates of human tickborne disease, the ultimate goal of our efforts is to identify modifiable behaviors of pet owners that can reduce tick encounters.

2. Purpose and Use of Information Collection

The data collection for which approval is sought will help DVBD:

- A) Understand current behaviors of pet owners and identify which pet-human interaction behaviors may increase the risk of human tick encounters among persons living in Lyme endemic areas
- B) Establish priorities for the prevention methods that should be evaluated in prospective cohort studies
- C) Develop targeted promotion of prevention methods that could yield substantial reductions in the incidence of tick-borne diseases (TBD)

The primary target population for these data collections is homeowners in areas where *I. scapularis* ticks transmit diseases to humans in three high incidence counties in Maryland.

Information will be collected electronically through web-based surveys.

Items of information to be collected include:

- Age of participating household member (Only those 18 and older are allowed to participate)
- Age, sex, size, and coat length of each indoor-outdoor dog and cat (up to five of each) in household
- Approximate time spent outside for each dog or cat

- History of tick exposure, tickborne disease, and Lyme vaccine use for each dog and history of tick exposure for each cat
- Frequency of certain human-pet interaction behaviors
- History of tick exposure among household members
- Use of pet-specific tick prevention products for each dog or cat
- Use of protective practices at the household level (e.g., cleaning, repellent use, yard-based tick control)

In addition, the addresses for participants (if the participant chooses to receive the token of appreciation) will be collected via email from the participant directly to MD EIP study coordinators at MDH.Pets@maryland.gov.

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.

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 or in-person interviews with project staff.

4. Efforts to Identify Duplication and Use of Similar Information

There are no similar, updated data available; that is, other institutions collecting information on human TBDs are not collecting this information as it relates to pet owner interactions with pets and their effect on human risk of tick bites and tickborne disease in Lyme disease endemic areas. 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

Respondents will be pet owners ≥ 18 years of age. In order to efficiently recruit pet owners, we will ask veterinary clinics and county rabies clinics to allow us to place recruitment materials in their locations. We will not ask clinics to participate directly in recruitment, answer pet owners' questions about the survey, or assist with data collection. Veterinary clinics will be invited to participate by sending emails (Attachment 3) directly to veterinarians practicing in the three target counties (Harford, Howard, and Anne Arundel counties) using email addresses from the Maryland State Board of Veterinary Medical Examiners, by direct contact of corporate offices for selected veterinary chains, and through newsletters including the Maryland One Health Bulletin. These invitation emails will state that participation is voluntary and ask veterinary clinics to make invitation postcards available to their clients.

Facilitators of rabies clinics in Harford, Howard, and Anne Arundel counties will be contacted by investigators at Maryland Department of Health to ask about participating by distributing invitation postcards to patrons of the low-cost rabies clinics.

Participation by veterinary clinics and rabies clinics to help us recruit respondents to our survey is voluntary and should not significantly impact their regular operations in any way.

6. Consequences of Collecting the Information Less Frequently

This is a one-time information collection. The timing of conducting this survey in fall months is critical due to the seasonal nature of tick activity and tickborne disease transmission. It is important for us to conduct this survey in the fall because we will ask respondents about tick exposures among pets and household members during the preceding six months, which corresponds with the highest risk times for tick encounters and tickborne disease.

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.

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:

Yale School of Public Health

Jim Meek (2014-2016)

Associate Director of Yale Emerging Infections Program

203.764.4364, james.meek@yale.edu

Sara Niesobecki (2014-2016)

TickNET Program Coordinator

203.764.7247, sara.niesobecki@yale.edu

U.S. Department of Defense

Ellen Stromdahl (2014-2016)

Entomologist, U.S. Army Public Health Command

410.436.5421, ellen.y.stromdahl.civ@mail.mil

9. Explanation of Any Payment or Gift to Respondents

After completion of the survey, participants will be mailed a thank you letter (Attachment 4) with a \$10 gift card to a local store as a token of appreciation for their participation. The token of appreciation will not be provided to individuals who begin the survey but are deemed ineligible.

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. 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 and IRB approval has been granted for the collection of data from human subjects.

Information in Identifiable Form

Responses will be kept private. Data management and storage related to recruitment, participation, and study organization will be maintained at the MD EIP site. Responsibility for maintaining confidentiality regarding participant information and survey data lies within the respective EIP site. Only coded data without direct personal identifiers will be shared with CDC for data analysis. The survey data will be maintained by MD EIP personnel in a secured REDCap database hosted by Yale University accessible by MD EIP investigators, CDC investigators, and Yale University REDCap administrators. This central data repository will contain only coded survey data which will be linked to the participant only by unique access codes and recruitment IDs; therefore, CDC investigators and Yale REDCap administrators will not have access to MD respondents' personally identifiable information. MD EIP personnel will store a separate spreadsheet linking the unique access codes and recruitment IDs to participants' names and addresses on a secure MDH server, separate from the REDCap database. Copies of electronic and paper files will be kept at the EIP site. All participant tracking and follow-up will be completed at the MD EIP site.

Personally identifiable information will be obtained by MD EIP personnel in the following ways: 1) if the participant chooses to be contacted for future studies related to pet ownership and tickborne diseases, they will email MD EIP personnel directly and their email address will be stored; 2) the addresses for participants (if the participant chooses to receive the \$10 gift card) will be collected via email from the participant to MD EIP personnel; and 3) name and addresses purchased and extracted from a commercial marketing database called Salesgenie will be stored and used for the direct mailing recruitment method.

Only the MD EIP study personnel will have access to personally identifiable information.

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

Institutional Review Board

CDC's Human Research Protection Office has reviewed the proposed information collection and determined on September 7th, 2017 that it is exempt under 45 CFR 46.101(b)(2) (protocol number: 7049) (Attachment 5).

Justification for Sensitive Questions

No sensitive questions are included in this information collection request.

12. Estimates of Annualized Burden hours and costs:

The number of screen-outs is expected to be zero because the recruitment materials clearly state eligibility criteria. In this study, participants will complete one web-based survey (Attachment 1).

Attachment 1 shows the OMB control number and burden statement on the first page. The survey will take up to 30 minutes to complete. We aim to enroll up to 500 participants. The estimated number of annualized burden hours is 250.

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
Pet owners in MD	PETs Survey	500	1	30/60	250
Total					250

Estimated Annualized Burden Costs to Respondents.

The total annualized burden cost is estimated to be \$14,316. 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) for “All Occupations.”

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Pet owners in MD	PETs Survey	250	\$23.86	\$5,965
Total				\$5,965

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.

		Total (\$)
Federal Government Personnel Costs	CDC Project Officer (GS-13 at 0.1 FTE)	\$10,536
	CDC Data Manager (GS-11, 0.25 FTE)	\$16,306
Subtotal, Federal Direct Costs		\$26,842
Cooperative Agreement	Cooperative agreement for implementation and information management	\$50,000
Total Annualized Cost to Government		\$76,842

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.

A.16 - 1 Project Time Schedule	
Activity	Time Schedule
Survey administered	1-2 weeks after OMB approval of Gen-IC
Data cleaning and validation	3-6 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.

List of Attachments

1. Survey
2. Introductory postcard
3. Veterinarian recruitment letter
4. Thank you letter
5. IRB Determination
6. Withdrawal letter
7. Social Media Advertisement