

Supporting Statement A for Request for Generic Clearance:

**Lyme and other Tickborne Diseases Knowledge, Attitude,
and Practice Surveys**

Extension Without Change of Previously Approved Information
Collection Request

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- **Goal of the study:** It is the goal of the Division of Vector-Borne Diseases (DVBD) to conduct surveys to evaluate knowledge, attitudes, and practices (KAP) regarding ticks and tickborne diseases (TBDs) among residents and businesses offering pest control services in Lyme disease endemic areas of the United States.
- **Intended use of the resulting data:** The data collection for which approval is sought will allow DVBD to use survey results to inform implementation of future TBD prevention interventions.
- **Methods to be used to collect:** DVBD and partners will conduct surveys using various methods including interviewer administered or self-administered surveys conducted via telephone, internet, or paper.
- **Subpopulation to be studied:** The primary target population for these data collections are individuals and their household members who are at risk for TBDs associated with *Ixodes scapularis* ticks and who may be exposed to these ticks residentially, recreationally, and/or occupationally. The secondary target population includes owners and employees of businesses offering pest control services to residents in areas where *I. scapularis* ticks transmit diseases to humans.
- **How data will be analyzed:** We will conduct descriptive statistical analyses for survey responses to establish baseline levels of TBD KAPs by homeowners and pest control operators (PCOs). We will also determine whether use of certain tick bite prevention practices is correlated with level of knowledge or concern regarding TBDs and/or tick exposures.

Supporting Statement A

An extension without change is requested for the “generic” three-year OMB clearance called “Lyme and other Tickborne Diseases Knowledge, Attitudes, and Practices Surveys.” Approval of this generic will facilitate implementation of data collection projects that allow us to better understand the knowledge, attitudes, and practices regarding ticks, TBDs, and TBD prevention in specific regions of the United States. This generic clearance request encompasses survey development, pre-testing activities, and survey administration to be carried out 2020-2022 in the Division of Vector-Borne Diseases (DVBD), National Center for Emerging and Zoonotic Diseases (NCEZID), Centers for Disease Control and Prevention (CDC). The activities will be conducted by the staff of DVBD and partners in the Division of Parasitic Diseases and Malaria, the Emerging Infections Program (EIP), or other grantees. These activities involve the development and administration of surveys related to TBD knowledge, risk factors, risk perception, prevention practices, and availability of prevention practices for residents in high risk areas. The results of these surveys will inform future randomized, controlled, TBD prevention trials. However, randomized controlled trials fall outside the scope of this generic package and will necessitate separate OMB review. This collection is not designed to develop incidence or prevalence estimates - collections under this ICR are not intended to yield results that are statistically projectable, nationally representative, or precise estimates of population parameters. Information gathered under this OMB clearance will not be used for the purpose of substantially informing influential policy decisions.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) Division of Vector-Borne Diseases (DVBD) and other programs working on TBDs is requesting a three year extension of approval for a generic clearance to conduct KAP surveys regarding TBDs such as Lyme disease, anaplasmosis, and babesiosis. The data collection for which approval is sought will allow DVBD to use survey results to inform implementation of future TBD prevention interventions.

Section 301 of the Public Health Service (PHS) Act (42 USC 241) (Attachment 1) 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.

TBDs are a substantial and growing public health problem in the United States. From 2004-2016, over 490,000 cases of TBDs were reported to CDC, including cases of anaplasmosis, babesiosis, ehrlichiosis, Lyme disease, Rocky Mountain spotted fever, and tularemia (CDC, 2018). Lyme disease accounted for 82% of all TBDs, with over 400,000 cases reported during this time

period. In addition, several novel tickborne pathogens have recently been found to cause human disease in the United States. Factors driving the emergence of TBDs are not well defined and current prevention methods have been insufficient to curb the increase in cases. Data is lacking on how often certain prevention measures are used by individuals at risk as well as what the barriers to using certain prevention measure are.

The primary target population for these data collections are individuals and their household members who are at risk for TBDs associated with *I. scapularis* ticks and who may be exposed to these ticks residentially, recreationally, and/or occupationally. The secondary target population includes owners and employees of businesses offering pest control services to residents in areas where *I. scapularis* ticks transmit diseases to humans. Specifically, these target populations include those residing or working in the 15 highest incidence states for Lyme disease (CT, DE, ME, MD, MA, MN, NH, NJ, NY, PA, RI, VT, VA, WI and WV).

This information request is being submitted for an extension without change of an already approved “Generic” clearance that provides the flexibility to conduct multiple surveys on the same topic (TBDs), but regarding different prevention methods, objectives, or target audiences. We anticipate conducting one to two surveys per year, for a maximum of six surveys conducted over a three year period. Depending on the survey, we aim to enroll 500-2000 participants per study. Each proposed information collection will submit an IRB application to determine whether or not approval is necessary. It is expected that we will need to target recruitment to about twice as many people as we intend to enroll (i.e., we anticipate a response rate of 50%. Surveys may be conducted daily, weekly, monthly, or bi-monthly per participant for a defined period of time (whether by phone or web survey), depending on the survey or study. For several planned surveys, it will be important to collect KAP information at multiple time points (daily, weekly, monthly) to be able to evaluate the variability in several measures. For example, the way a person interacts with their environment, and thus their risk for tick encounters, changes over the course of a summer. Their use of tick control products or repellent is thought to vary greatly (potentially due to the fatigue of repeated applications or, perhaps, due to their perception of risk declining). By collecting frequent information regarding how a person uses their yard, we would have better information regarding the areas of their yard presenting greatest risk. The surveys will range in duration from approximately 5-30 minutes. Each participant may be surveyed 1-64 times in one year; this variance is due to differences in the type of information collected for a given survey. Specific burden estimates for each study and each information collection instrument will be provided with each individual project submission for OMB review. There is no cost to respondents other than their time.

Insights gained from KAP surveys will aid in prioritizing which prevention methods should be evaluated in future randomized, controlled trials and ultimately help target promotion of proven prevention methods that could yield substantial reductions in TBD incidence.

Overview of the Data Collection System

Depending on the individual information collection request, information might be collected using the following modes: focus groups, in-person interviews (face-to-face or via telephone), paper-

and-pencil questionnaires, or electronically. Electronic modes may include handheld devices, web-based surveys (including use of applications on participants' mobile devices), or other point-of-service collection devices.

Items of Information to be Collected

Data collection will be limited to high-risk populations in specific geographic areas in the United States.

Items of information to be collected include:

- Socio-demographics (e.g., age, gender, occupation, education, income)
- Self-reported previous history of TBD in respondent or among household members and perception of TBD risk
- Knowledge, attitudes, and practices related to ticks and TBDs
- Willingness to pay for certain prevention methods

Specific target populations that are within the scope of this Generic include populations in areas of high Lyme disease and other TBD incidence, specifically:

- those living in CT, DE, ME, MD, MA, MN, NH, NJ, NY, PA, RI, VT, VA, WI, WV or counties with high incidence for Lyme disease in other states
- Target populations may include households, depending on the individual project
- Target populations may include individuals, depending on the individual project
- Target populations may include those who are at risk of TBDs residentially, recreationally, and/ or occupationally.
- Target populations may include business owners and/or employees who provide pest control services, depending on the individual project

Description of Previous Information Collections under this Generic Clearance (during 2016-2019)

At the time of this extension request, five separate surveys have been approved under this generic information collection.

Two of these surveys were targeted to pest control operators in the mid-Atlantic/northeastern U.S. The first was conducted in New Jersey under a CDC-funded contract in the summer of 2017. It aimed to enroll no more than 850 respondents. The second very similar effort was conducted in New York and Pennsylvania under contract in 2017/2018 and aimed to enroll no more than 1,700 respondents. Ultimately, these two efforts collected survey data from 290 individuals.

A third approved survey was administered to pet owners living in areas endemic for Lyme disease in Maryland. It was conducted by CDC and its Emerging Infections Program (EIP) Cooperative Agreement partners in 2017. These investigators aimed to enroll 500 respondents and provided small tokens of appreciation for participation. The last (very recently approved) survey has not yet been administered, but will be targeted to healthcare professionals working in

schools in New York state and Maryland. It is also being conducted by CDC and its Emerging Infections Program (EIP) Cooperative Agreement partners. It is due to be administered in May of 2019 and will collect information from up to 3,951 respondents.

The fifth gen-IC – Upper Midwest Tickborne Disease Prevention Survey – was approved in July, 2019. The goal of this project will be to characterize the current tickborne disease knowledge and disease prevention behaviors practiced by the public in the upper Midwest, including willingness to conduct or pay for specific tick control methods.

The forms used to collect information in these studies are all posted on the Office of Information and Regulatory Affairs website at: https://www.reginfo.gov/public/do/PRAICList?ref_nbr=201606-0920-021.

2. Purpose and Use of Information Collection

The information collected under this generic will be used by DVBD and other CDC personnel, state and local public health practitioners, and academicians to inform current and future TBD prevention programs. Many TBD prevention methods are currently available and promoted by public health practitioners, but their level of use and/or barriers to use are not well known. As cases of TBDs continue to rise, there is a great need to identify effective prevention methods that people will be willing to use and can afford to implement.

This ICR is being submitted as an extension of a generic ICR pertaining to surveys planned over the next 3 years, but not yet developed, regarding the knowledge, attitudes, and practices of the public in relation to ticks, TBDs, and TBD prevention. It is anticipated that these future surveys will use similar questions and formatting, though will vary somewhat due to the objectives, scope of the project or target population. Attachments (pg. 16) 3-9 are from a previous effort conducted under this generic ICR and are provided as an example of these future information collection efforts. Each proposed information collection will submit the tools used for data collection in the request provided to OMB.

- Purpose: Evaluate the public's knowledge, attitudes, and practices regarding ticks, TBDs, and TBD prevention.
- Use: Tailor prevention interventions based on results of KAP surveys

Examples of the data collection, topics and specific target populations that are within the scope of this Generic include:

- Conduct surveys to establish baseline use and/or barriers to use of certain prevention methods by individuals (e.g., repellent, permethrin treated clothing, pet tick control) or by pest control operators (e.g., chemical or natural acaricide applications, rodent targeted bait boxes, landscape modification)
- Conduct surveys to monitor changes in use of these methods over time (i.e. over a season or in response to changing risk perception) or among different high-risk areas.
- Conduct surveys to measure use of prevention methods and exposure to ticks or TBDs.

- Conduct surveys to assess willingness to receive a Lyme disease vaccine for humans if one were to become available.
- Conduct surveys of outdoor behavior to determine most likely areas of exposure to ticks (e.g. peridomestic vs. recreational environments vs. wood-lawn interface vs. garden).

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. For some individual projects, potential participants may be excluded based on a lack of email address since use of email is critical for many 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. Though these technologies will be used by many of the individual projects in this data collection, the nature of some of the proposed activities requires direct interaction between respondents and project staff. This is especially true for the first contact between potential respondents and project staff, as this typically involves assessing respondents' eligibility for the study, explaining study details, answering any questions the potential respondent may have, and gaining verbal consent for continued participation. In addition, some exceptions may be made so that populations who may not typically use email (e.g., the elderly) may be enrolled with the option to correspond with study staff via phone only. This exception will depend on the individual project, but may be necessary in order to enroll a representative sample and/or certain populations at risk of TBD.

Individual data collections to be conducted under this generic package will provide detailed information about the proposed data collection tools and how they use information technology, when feasible, to reduce burden. Each proposed information collection will submit the tools used for data collection in the statement provided to OMB. They will also provide details on the type of information collected. The number of questions posed will be held to the minimum required in all information collections in order to elicit the necessary data.

4. Efforts to Identify Duplication and Use of Similar Information

There are no similar data available; that is, other institutions collecting information on human TBDS are not collecting this information as it relates to KAP surveys on *I. scapularis* transmitted diseases. DVBD has verified through RegInfo.gov that there are no other federal generic collections that duplicate information collection for TBD research included in this request. We used the following search terms to identify other ICRs that may involve a duplication of efforts: tick-borne disease, tickborne disease, *Ixodes scapularis*, Lyme disease, anaplasmosis, and babesiosis. In addition, from DVBD's participation in two working groups with other federal agencies (HHS Lyme and other TBDS Working Group: CDC, FDA, NIH; Federal TBD Integrated Pest Management Working Group: CDC, EPA, USDA, NIH, DOD, USGS, NSF), we

know that no other federal agencies are conducting TBD KAP surveys. Lastly, we have attended \geq two national conferences per year and conducted extensive literature searches using online databases (such as PubMed) to verify that similar data collections are not being conducted by other institutions, whether federal, academic, industry, or otherwise. CDC published the results of a nationwide survey in 2015 that reported on the U.S. public's knowledge, attitudes, and behaviors regarding ticks and tickborne diseases (Hook et al. 2015, "U.S. Public's Experience with Ticks and Tick-borne Diseases: Results from national HealthStyles surveys." *Ticks and Tick-borne Diseases*). However, this study reported results at the national and regional levels, and it was not determined whether the sample population surveyed were at risk of TBDs. The proposed information collections will improve upon these results by allowing data collection at targeted, at-risk communities at a finer scale, that is, the state, county, or town level.

5. Impact on Small Businesses and Other Small Entities

Some activities involve data collection from small businesses, namely, pest control companies since they are our secondary target population. If such activities are conducted, these businesses will be approached in the same manner as the individuals we normally recruit: we will ask the organization to identify the appropriate staff members with whom to conduct the activities. In these examples, small businesses should not be adversely affected by the research being conducted.

6. Consequences of Collecting the Information Less Frequently

There are no legal obstacles to reduce the burden.

The consequence to DVBD if the information collections in this request are not conducted are as outlined in section A.2. "Purpose and Use of Information Collection." Each individual project will require information collections at different times, and some of these collections may be time sensitive based on the seasonality of TBDs, which is dictated by the complex ecological cycle of *I. scapularis* ticks and their rodent hosts.

Conducting information collections less frequently than detailed in the individual projects may result in invalid or lost data on the outcomes of interest because of inappropriate timing of the collections. For example, having less frequent surveys, in some cases, means having more participants lost to attrition which can affect the generalizability (and power) of study results.

While the frequency of information collection will vary among individual projects (e.g., responses may be requested annually, quarterly, weekly, or daily), all individual projects under this Generic will occur only one time, i.e., we do not plan to conduct the same survey on the same study population more than once.

7. Special Circumstances Relating to Guidelines of 5 CFR 1320.5

This information collection request may require respondents to report information to study staff more often than quarterly, depending on the individual project. For example, in a survey collecting information on use of personal protective measures (e.g., use of repellent or permethrin treated clothing), it may be necessary to know if the participant practiced these measures when outside in tick habitat and whether the participant encountered ticks. During tick season (i.e., summer), the participant may be outside in tick habitat every day. Alternatively, if the goal of the study is to determine barriers to use of certain prevention methods, a one-time information collection will be sufficient.

The following special circumstances do not apply to this information collection request:

- Requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Requiring respondents to submit more than an original and two copies of any document.
- Requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- In connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- Requiring the use of a statistical data classification that has not been reviewed and approved by OMB;
- That includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

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

A. A 60-Day Federal Register Notice was published in the Federal Register on June 5, 2019, Vol. 84, No. 108, pp. 26109-26110 (Attachment 2). One non-substantive public comment was received (attachment 2a).

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 generic clearance package:

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

9. Explanation of Any Payment or Gift to Respondents

CDC understands that the default for these types of collections is not to offer incentives. For the proposed information collections, respondents will often be recruited for specific characteristics (e.g., questions may be relevant only to people living in certain areas or with certain yard characteristics). The more specific the target population, the more difficult it is to recruit eligible respondents; as such small incentives may be necessary in limited situations (e.g., when the participant must travel to a facility to participate). Requests and justification for incentives will be included in each individual collection submission.

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 **may apply depending on the specific gen-IC**. 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, as well as EIP partners receive appropriate annual privacy and confidentiality training.

10.1 Privacy Impact Assessment Information

- A. Each individual request under this generic clearance will provide adequate descriptions of information systems that will be used in their study.
- B. Electronic data will be kept on the project-specific network on a secure server, which is accessible only to users granted rights by the project director and in a secure location with restricted physical access to staff working on the project only.
- C. Participation in formative research information collection activities is strictly voluntary. All human subjects regulations will be followed. For some projects, participants may need to provide informed consent (e.g., Attachment 4). In such cases, respondents will be provided with an informed consent form prior to the start of information collection, and will be allowed to ask questions about the project before deciding whether to participate or not. The consent form will describe the purpose of the study, specifies specific procedures that will be conducted, and protections for the respondent's privacy. Each individual data collection request will provide informed consent forms if required by CDC's or another participating agency's IRB.
- D. Some of the individual data collection activities will require respondents to provide

identifying or potentially identifying information to project staff. If applicable, persons participating in such projects conducted by DVBD will be informed that their data will be maintained in a secure manner and that the data will only be used for purposes stated in the consent form. Personally identifiable information will be removed from any data sent to CDC, and CDC will at no time have access to any data that contains identifiers. Project staff will verify that any identifying information that has been collected during the course of their activities has been removed from information transmitted to or shared with CDC. Only authorized project staff will be allowed to have access to study information (whether identifiable or not) and all information stored in hard copy will be kept in a locked cabinet and/or locked office with limited access.

Information in Identifiable Form

Information in identifiable form will be collected for linkage of various forms (e.g., informed consent documentation, enrollment information, surveys). For any project covered under this proposed generic clearance, collection of any personally identifiable information will be collected by local partners (e.g., EIP collaborators) or CDC personnel, either in-person or over the telephone. Web-based methods for survey delivery may also be evaluated under this generic approval and may involve use of participants' email addresses in order to conduct the evaluation. Individual collection requests submitted under this generic approval will describe the specifics of how this information is handled.

The identifiable information includes:

- Name
- Phone Number
- Address
- Email

Documentation of data collection activities will be provided with each individual data collection request.

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

Because methods and materials may differ between individual projects, appropriate human subjects review procedures will be conducted for each individual project as they are developed. Projects that need IRB approval will be submitted with a copy of the approval document from each participating institution (e.g., EIP sites, academic partners, other federal partners). Each project will be conducted according to the local and state laws in existence where the project is being conducted for the protection of the rights of human volunteers. If any project is officially waived from IRB review, we will attach a copy of the waiver letter.

No sensitive questions are anticipated for the topics planned in this information collection request. However, any collection of a sensitive nature will be described in that individual data collection submission.

The possibility exists that respondents may find certain questions from the surveys to be sensitive in nature. However, questions covering such topics as demographics, activity locations, and health history are typical components of medical examinations. These questions are necessary to identify potential risk factors for exposure to ticks and TBDs. Questions regarding classification of yard and personal behaviors regarding tick bite protection would not be considered sensitive. 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:

As with the previously approved genIC, we anticipate beginning one to two studies per year, for a maximum of six studies conducted over a three year period. Depending on the intervention being assessed, we aim to enroll 500-10,000 participants per study. It is expected that we will need to recruit about twice as many people as we intend to enroll in order to evaluate them for interest and eligibility, hence the higher number of respondents listed for the screening form. Surveys may be conducted daily, weekly, monthly, or bi-monthly for a defined period of time (whether by phone or web survey). Surveys may take a minimum of 5 minutes and a maximum of 30 minutes to complete. Each participant may be surveyed 1-64 times in one year; this variance is due to differences in the type of information collected for a given study. For example, a single survey may be conducted among the population at risk to assess KAPs regarding a certain intervention before that intervention is later tested in a RCT using human outcomes. Or, a study may include an introductory survey, a brief, daily collection of prevention practice data for up to two months (60 surveys), plus two follow up surveys, and a final survey (4 surveys) for a possibility of 64 surveys maximum. These examples represent the minimum and maximum data collections possible; most studies will require data collections somewhere between these parameters. Specific burden estimates for each study and each information collection instrument will be provided with each individual project submission for OMB review.

The estimates of annualized burden hours are based on knowledge of similar studies. The maximum estimated, annualized burden hours are 9,583 hours. There is no cost to respondents other than their time.

Estimated Annualized Burden Table

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
General public, individuals or households	Screening instrument (Attachment 3)	4,000	1	15/60	1,000

	Consent form (Attachment 4)	2,000	1	10/60	333
	Introductory Surveys (Attachment 5)	2,000	1	30/60	1,000
	Monthly surveys (Attachment 6)	2,000	12	15/60	6,000
	Final surveys (Attachment 7)	2,000	1	30/60	1,000
Pest Control Operators	PCO Survey (Attachment 9)	500	1	30/60	250
Total					9,583

Estimated Annualized Burden Costs to Respondents.

The average annual response burden cost is estimated to be **\$237,698.34**. The hourly wage estimate is based on the Bureau of Labor Statistics May 2018 National Occupational Employment and Wage Estimates for All Occupations (http://www.bls.gov/oes/current/oes_nat.htm).

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General public, individuals or households	Screening instrument	1,000	\$24.98	\$24,980.00
	Consent form	333	\$24.98	\$8,318.34
	Introductory Surveys	1,000	\$24.98	\$24,980.00
	Monthly surveys	6,000	\$24.98	\$149,880.00
	Final surveys	1,000	\$24.98	\$24,980.00
PCOs	PCO survey	250	\$18.24	\$4,560.00
Total				\$237,698.34

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

Actual annualized costs to the government will vary depending on the specific needs of the individual information collection activity. Generally, each development activity will involve participation of at least one CDC project officer and one CDC study coordinator who will be responsible for the project design, obtaining IRB approvals, providing project oversight, and analysis and dissemination of the results. These two positions will provide remote and onsite technical assistance to the local areas implementing the data collection. Travel may be required to provide this technical assistance. Estimated costs for cooperative agreements with EIP sites include local support staff personnel costs (0.5-3 FTEs per site, up to 5 sites), overhead, data collection costs (printing, IT, phone), and some local travel costs. While actual annualized costs will vary depending on the scope of future submissions, it is estimated that the annual cost to the Federal Government is **\$653,000**. Detailed costs will be submitted with each individual data collection activity.

Governmental Costs

		Total (\$)
Federal Government Personnel Costs	CDC Project Officer (GS-12/13/14 at 0.75 FTE)	\$75,000
	CDC Data Manager (GS-9/11, 1.0 FTE)	\$63,000
	CDC Travel (8 trips)	\$15,000
Subtotal, Federal Direct Costs		\$153,000
Cooperative Agreement or Contract	Cooperative Agreements, Task orders, or Contracts for implementation or information management	\$500,000
Total Annualized Cost to Government		\$653,000

15. Explanation for Program Changes or Adjustments

This is an extension without change of a previously approved information collection Program changes and adjustments are not being requested at this time.

16. Plans for Tabulation and Publication and Project Time Schedule

An estimated project time schedule for a one-year study is outlined below. Individual project time schedules will be submitted for individual data collection requests.

A.16 - 1 Project Time Schedule	
Activity	Time Schedule
Recruitment letters sent to respondents	1 - 2 months after OMB approval of Gen-IC
Consent form and Introductory survey conducted	1-2 months after OMB approval of Gen-IC
Monthly surveys administered	3-9 months after OMB approval of Gen-IC
Final survey administered	9 months after OMB approval of Gen-IC
Data cleaning and validation	10 - 12 months after OMB approval of Gen-IC
Analyses	12 - 18 months after OMB approval of Gen-IC

Individual data collections under this generic approval will be time-limited and generally conducted only once, except in the cases where the study may be conducted again in a different area to assess any geographic differences. Data collection activities will take less than one year to complete. Proposed timelines will be submitted for each individual data collection activity.

The analysis plan will vary for each individual project; however, for most studies descriptive analyses of survey information will be performed to describe the general demographics, TBD history, landscape characteristics and KAPs of participants in regards to TBDs. Tick encounters (tick found attached/crawling on participants and pets) over the course of the study will be evaluated for differences based on reported prevention practices. Regression techniques may be used to evaluate any differences in time and location for those people reporting tick encounters as compared to those that do not.

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.

Attachments

1. Authorizing legislation
2. 60-day FRN
3. Screening instrument
4. Consent form

5. Introductory surveys
6. Monthly surveys
7. Final surveys
8. Daily surveys
9. PCO surveys