Supporting Statement B of the Request for Generic Clearance:

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

OMB Control No. 0920-1150

Revision of Previously Approved Information Collection Request

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B. Collections of Information Employing Statistical Methods

This request is a revision for a generic collection, which involves sample surveys for formative research studies conducted among samples of populations at risk for tickborne diseases (TBDs).

The intention is to continue to draw inferences from the results of these studies that that will inform future public health studies to be conducted on populations at risk for TBDs, including but not limited to Lyme disease, anaplasmosis, and babesiosis. 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.

1. Respondent Universe and Sampling Methods

The target population for these data collections are individuals and their household members who are at risk for TBDs associated with *Ixodes scapularis* ticks. Specifically, this target population includes those living in the 15 states with the highest incidence of Lyme disease (CT, DE, ME, MD, MA, MN, NH, NJ, NY, PA, RI, VT, VA, WI, WV). Surveys may be targeted at the individual, household, or other organizational level and may focus on those who are residentially, recreationally, and/or occupationally exposed to *I. scapularis* ticks. For example, depending on the survey, households with certain property characteristics may be targeted (e.g., forested edge in yard indicating tick habitat) or individuals with certain risk factors may be targeted (e.g., age, past TBD diagnoses, etc.). In addition, pest control businesses may be surveyed regarding the type of prevention products they offer. The number of households, individuals, or organizations sampled depends on the outcome of interest (e.g., prevalence of using a certain prevention method, tick exposures) for a particular survey and the power calculation (described below in #2).

As an example of a survey, Gould et al. (2007) conducted a study to assess knowledge, attitudes, and behaviors regarding Lyme disease prevention among Connecticut residents. A random cross-section of approximately 400 households in each of 3 health districts was selected during each year of the study (Gould et al., 2007). The sample frame consisted of telephone exchanges covering the towns of interest, including all exchanges in which at least 95% of all numbers were part of the target geography. The final sample was selected using simple random sampling without replacement. Selected telephone numbers were contacted at least four times to reach an eligible respondent. A respondent was considered eligible if he or she was 18 years of age or older and the household healthcare decision maker. In total, 2806 interviews were completed for this study over 3 years (100% of target enrollment in each district in each year).

2. Procedures for the Collection of Information

The proposed studies will be conducted as knowledge, attitude, and practices (KAP) surveys. Study coordinators will identify all residents living in selected target areas. In the case of household or individuals targeted for recruitment, mailing addresses and names for prospective participants will be

extracted by state and local health department personnel through records maintained by public records and/or commercial marketing databases (e.g., Infogroup). This information may also be combined with the results of geographic information systems (GIS) evaluations to identify households that fall within the predetermined geography for high-risk areas. For pest control businesses, business contact information will be acquired through internet searches. Once selected, we will then send recruitment letters or flyers to these targeted groups to solicit interested participants.

For one-time surveys, all persons who indicate interest in study participation by mail, phone, email or the web will be sent a survey, whether electronic, phone-based, or paper-based. These surveys will be designed to collect information on demographics, knowledge and history of TBDs, TBD prevention knowledge and practices, and tick exposures. If participants do not submit or complete surveys within two weeks of receipt, they will be re-contacted up to 4 times by email or text message (if phone number is available) and reminded to complete the survey.

For more complex daily, weekly, or monthly surveys, all persons who indicate interest in study participation by mail, phone, email or the web will be contacted by trained study coordinators, who will schedule a time to speak with the individual over the phone to discuss the study, determine eligibility, request permission to mail study forms to their home for their review and signature (if needed), and obtain verbal consent to complete the introductory survey.

The daily, weekly, or monthly surveys are designed to collect information that changes over time. In vector-borne disease epidemiology, it is expected that changes occur in people's attitudes and behavior over a single summer or transmission season. This may be due to a number of factors, for instance: changes in the number of ticks present in the environment, the occurrence of disease in a household, or fatigue with performing prevention behaviors after every visit outdoors (e.g., tick checks). To target prevention efforts, we would need a better understanding, for a given community, of people's risk perception and willingness to practice any prevention measure over a given season.

The introductory surveys are designed to collect information on demographics, landscape features, and measures of TBD risk on the household and individual (respondent only) levels. Information to geolocate the house will also be collected (address or GPS location). In addition, short self-administered surveys will be given to participants electronically at select intervals (e.g., daily, weekly, monthly, or biannually) throughout enrollment. These surveys will collect information regarding the type of prevention practice performed and number and type of ticks found crawling or attached on household members or pets over a specified time period (e.g., the last month) or if any participants had been diagnosed as having a TBD. Study personnel will administer surveys by phone to all those who will not be able to complete any survey electronically. Information regarding TBD will include onset date, clinical symptoms, prescribed treatment, and diagnosing provider.

Sample Size Estimation

Sample Size Estimates for Tickborne Diseases KAP Surveys:

Table 1: Sample size calculation for % frequency in a population; Example: Prevention practices

Prevention practice	Anticipated frequency (%)*	Confidence (%)	Number of individuals or households in sample**

Repellent use	25	95	289
Showering	19	95	237
Tick checks	43	95	377
Yard-based pesticide	7	95	101
Rodent-targeted bait boxes	1	95	16
Permethrin treated clothing	3	95	45

[*]Based on 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*. The proposed information collections will improve upon these numbers by allowing data collection at a finer scale, that is, the state, county, or town level.

[**]Our proposed range of respondents for these information collections is 500-10,000 (see Supporting Statement A). This range accounts for the sample sizes estimated above being achieved in several different geographic areas (e.g., multiple states).

3. Methods to Maximize Response Rates and Deal with Nonresponse

As mentioned above, in a previous knowledge, attitudes, and behaviors survey by Gould et al. (2007), target enrollment (400 households per district per year) was achieved throughout the study. 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.

For KAP surveys, in general, if participants do not submit or complete the survey within two weeks of receipt, they will be re-contacted up to 4 times by email or text message (if phone number is available) and reminded to complete the survey in order to maximize response rates. Specific plans for maximizing response rates and dealing with nonresponse will be outlined in each individual data collection request.

In general, substudies that are submitted under this Generic pathway are 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.

4. Tests of Procedures or Methods to be Undertaken

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

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

All persons listed below may be involved in design, collection and analysis of proposed data

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