

**LYME AND OTHER TICKBORNE DISEASES
PREVENTION STUDIES (LTDPS):
Upper Midwest Tickborne Disease Prevention Survey**

Supporting Statement A for a New Generic Information Collection
Request

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Contact Information:
Nancy Khalil, J.D.
Office of Policy and Planning
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road, NE, MS H16-5
Atlanta, Georgia 30333
Phone: (770) 488-2070
Fax: (678) 475-4540
Email: kuj2@cdc.gov

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- **Goal of the project:** 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.
- **Intended use of the resulting data:** The intent is to collect baseline data prior to future tick control efforts and to determine what methods and practices are feasible in the region. We will also identify motivations for and barriers to implementation of tickborne disease prevention methods, which will inform future communication and education efforts to the public.
- **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 among “high risk” counties in MI, MN, and WI. “High risk” counties are defined as counties with a five-year average (2013-2017) Lyme disease incidence ≥ 10 cases per 100,000 persons. One adult from each residence will be selected to respond to the survey based on who in the household had the most recent birthday, which is an established technique to approximate random sampling. The final sample is expected to be representative of the populations with highest tickborne disease risk within these three states, in the absence of non-response.
- **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 partners with the Midwest Center of Excellence for Vectorborne Disease (MCE-VBD) and TickNET are requesting approval for a generic information collection (gen-IC) to conduct surveys on public knowledge, attitudes, and behaviors (KAB) regarding tick bite prevention and tickborne diseases (TBD) in the upper Midwest.

Tickborne diseases such as Lyme disease (LD) are considered endemic to the upper Midwest, affecting large portions of Minnesota and Wisconsin as well as expanding areas in Michigan. In 2017, Minnesota and Wisconsin were two of 16 states considered to be high incidence for reported LD cases with 25 and 31 confirmed cases per 100,000 persons. Michigan is currently considered a low incidence state with 2 confirmed cases per 100,000 persons reported in 2017, although geographic expansion of the vector has raised concern about increases in LD and other tickborne diseases in this region. In addition to transmitting the LD agents *Borrelia burgdorferi sensu stricto* and *Borrelia mayonii*, a bite from an infected *Ixodes scapularis* tick can transmit agents of anaplasmosis, babesiosis, ehrlichiosis, Powassan virus disease, and relapsing fever due to *Borrelia miyamotoi* infection.

A cross-sectional survey on tickborne disease KAB across MI, WI, and MN would offer new insights into the latest attitudes toward LD and TBD prevention in this region. To our knowledge, no KAB study on LD and other TBD prevention on this scale has been performed in the upper Midwest. Questions on willingness to pay for personal protection measures and environmental tick control will be included on the survey and will offer crucial insights for the first time in this region. Comparisons between these states will also be analyzed which will inform diverse public health efforts on TBD knowledge and

disease prevention in each of these three states. Results from this survey will also provide baseline data to support the development of novel targeted public health interventions.

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 current knowledge, attitudes, and behaviors regarding TBD prevention in the upper Midwest. The results will be used to inform public health efforts on tickborne disease prevention in each of the three states (MN, WI, MI).

The primary target population for these data collections are adults within a random sample of households among “high risk” counties in MI, MN, and WI. “High risk” counties are defined as counties with a five-year average (2013-2017) LD incidence ≥ 10 cases per 100,000 persons (Attachment 1). One adult from each residence will be selected to respond to the survey based on who in the household had the most recent birthday, which is an established technique to approximate random sampling. The final sample is expected to be representative of the populations with highest tickborne disease risk within these three states, in the absence of non-response.

Information will be collected via web-based surveys (Attachment 4). An invitation postcard will be used for recruitment (Attachment 3). 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 5).

Items of information to be collected include:

- Age of the adult in the household answering the survey (i.e., the person about whom information will be collected)
- Knowledge and attitudes related to ticks and tickborne diseases (e.g., concern about getting a tickborne disease, tick exposure activity)
- Behaviors that are currently done to prevent tick bites and tickborne diseases, including any barriers to prevention methods that are not performed
- Behaviors that the respondent might be willing to do to prevent tick bites and tickborne diseases, including personal, household, and community-based prevention methods
- Whether the respondent would be willing to pay for tick control prevention measures, both household and community-based methods
- Reasons why the respondent would not be willing to practice or pay for tick control prevention measures (e.g. safety, cost, and efficacy)
- Additional demographics (gender, race, ethnicity, education, income)

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 (Attachment 4a). If not, the respondent will not be allowed to proceed. Potential participants will receive up to two reminders (Attachment 2) 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 human TBD are not collecting this information as it relates the knowledge, attitudes, and behaviors of the public in Midwestern LD high-risk counties regarding TBD prevention. 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 spring and summer 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/MCE-VBD investigators

Minnesota Department of Health

Jenna Bjork, Study Principal Investigator and Epidemiologist

Erin Kough, Health Program Representative

David Neitzel, Supervisor of Vectorborne Diseases Unit

Molly Peterson, Epidemiologist

Elizabeth Schiffman, Epidemiologist

MCE-VBD investigators

Michigan State University

Jean Tsao, Associate Professor Depts. of Fisheries & Wildlife and Large Animal Clinical Sciences

Michigan Department of Health and Human Services

Mary Grace Stobierski, Supervisor of Emerging & Zoonotic Infectious Diseases Section

Kimberly Signs, Zoonotic Disease Epidemiologist

Jennifer Sidge, Medical Ecologist

Erik Foster, Medical Entomologist

University of Wisconsin Madison

Lyric Bartholomay, Entomologist, Co-director of the MCE-VBD

Bieneke Bron, Postdoctoral Associate

Susan Paskewitz, Entomologist, Co-director of the MCE-VBD

Daniel Phaneuf, Agricultural and Applied Economist

Danielle Smith, Coordinator of the MCE-VBD

Wisconsin Department of Health Services

Julia Jensen, Epidemiologist

Christine Muganda, Epidemiologist

Rebecca Osborn, Epidemiologist

Ryan Wozniak, Supervisor of Vector-borne Disease Program

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 skip answers (as described in the survey instructions) 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 or do not understand English), they will not continue with the survey or receive gift cards as compensation for their time.

A previous KAB survey on public tickborne disease prevention, recently conducted in the Northeast, similarly provided a \$10 gift card to survey participants after completion of the survey. A total of 7% of respondents completed the survey (unpublished data, 2018). Based on this response rate, and the anticipated difficulty of recruitment for a similar target population, we believe the monetary amount to be contextually appropriate.

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 #7217) 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 May 15, 2019.

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 Minnesota Department of Health (MDH) network maintained by MDH'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. The state study coordinator will then mail these participants a withdrawal letter (Attachment 6) stating that 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 #7217) 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 May 15, 2019 (Attachment 8).

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 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 1977 participants or approximately 659 in each state (Minnesota, Wisconsin, and Michigan). The estimated number of annualized burden hours is 396 hours. The survey will contain a response limit of 1000 completed responses for each state.

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 high-risk LD counties in the Midwest	Upper Midwest Tickborne Disease Prevention Survey	1977	1	10/60	330
	Upper Midwest Tickborne Disease Prevention Survey – Screen out	3954	1	1/60	66
Total					396

Estimated Annualized Burden Costs to Respondents.

The average annual cost burden cost is estimated to be \$9,892.08. 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) for “All Occupations.”

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Adults of households in high-risk LD counties in the Midwest	Upper Midwest Tickborne Disease Prevention Survey	330	\$24.98	\$8,243.40
	Upper Midwest Tickborne Disease Prevention Survey – Screen out	66	\$24.98	\$1,648.68
Total				\$9,892.08

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

A.16 - 1 Project Time Schedule	
Activity	Time Schedule
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.