GenIC Clearance for CDC/ATSDR
Formative Research and Tool Development

Lyme Disease Creative and Message Testing Focus Groups

OMB Control No. 0920-1154

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Supporting Statement A

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- **Goals of the project:** To evaluate, validate, and refine up to four draft creative concept approaches and a set of potential educational messages about Lyme disease prevention among public audiences in high-risk and emerging risk areas for Lyme disease.
- **Intended use of the resulting data:** To inform the development of targeted communication strategies and materials about Lyme disease prevention intended for these audiences.
- **Methods to be used to collect data:** Eight online focus groups.
- **The subpopulation to be studied:** The subpopulation is be divided between 1) individuals living in high incidence states for Lyme disease and 2) individuals living in emerging incidence states. Within these subpopulations, the project will further focus on people who

are either active outdoors or parents of children aged 5-15.

- **How data will be analyzed:** Descriptive and thematic analyses of qualitative data.

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) is requesting approval for a new generic information collection (gen-IC), "Lyme Disease Creative and Message Testing Focus Groups." CDC has recognized the critical need for formative research to understand the perspectives, beliefs, and communication needs of key audiences regarding Lyme disease prevention. This project focuses on individuals residing in states with high and emerging incidence of Lyme disease, specifically targeting people active outdoors and parents of children aged 5-15. Understanding these audiences presents unique opportunities for improving CDC's communication strategy and furthering CDC's mission of protecting public health.

Lyme disease is a serious and growing public health issue in the United States. While surveillance reports indicated over 89,000 cases in 2023, an increase from previous years, recent estimates suggest approximately 476,000 people may be diagnosed and treated for Lyme disease annually.[1] If left untreated, the infection can lead to significant health problems affecting the joints, heart, and nervous system.[2] Actions like using insect repellent, wearing protective clothing, performing tick checks, and promptly removing ticks can help prevent infection.

However, challenges exist in ensuring the public effectively adopts and adheres to these preventative measures. Gaps in knowledge about Lyme disease, confusion stemming from misinformation, and varying perceptions of risk can hinder prevention efforts.[3,4] There is a need to understand how to best communicate prevention information in a way that resonates with and motivates populations that live and are active in high-incidence and emerging incidence areas.

While research has documented the scope of the problem, this project will test a set of draft creative concepts and educational messages for clarity, resonance, and impact among a specific priority audience as well as further assessing audience knowledge gaps and communication needs. Collecting data directly from target audiences in high and emerging incidence areas will enable NCEZID to identify effective communication approaches, refine messages and materials, optimize its communication strategies, and ultimately enhance its ability to safeguard public health by preventing Lyme disease.

2. Purpose and Use of Information Collection

[1] CDC, Lyme Disease Surveillance and Data, 2025. https://www.cdc.gov/lyme/data-research/facts-stats/index.html

[2] CDC, About Lyme Disease, 2025. https://www.cdc.gov/lyme/about/index.html

[3] Kopsco, Heather L et al. "Identifying Trusted Sources of Lyme Disease Prevention Information Among Internet Users Connected to Academic Public Health Resources: Internet-Based Survey Study." *JMIR formative research* vol. 7 e43516. 26 Jul. 2023, doi:10.2196/43516. https://pubmed.ncbi.nlm.nih.gov/37494089/

[4] Richardson, M et al. "Interventions to prevent Lyme disease in humans: A systematic review." *Preventive medicine reports* vol. 13 16-22. 13 Nov. 2018, doi:10.1016/j.pmedr.2018.11.004. https://pubmed.ncbi.nlm.nih.gov/30456054/

The goals of this one-time data collection are to 1) evaluate, validate, and refine up to four draft creative concept approaches about Lyme disease prevention, 2) test draft messaging related to these concepts, and 3) identify audience knowledge gaps about Lyme disease revealed during discussions. Attachment 5 includes the creative concepts and messages that will be tested.

In total, eight 90-minute online focus groups will be conducted. The groups will focus on individuals residing in states with either high or emerging incidence of Lyme disease. These regions were selected based on CDC priorities for reaching populations in priority areas. Four focus groups will be conducted with residents of high incidence states and four groups will be conducted with residents of emerging incidence states. Each geographic category will be further segmented to include one group for each of the following high-risk audiences to ensure a breadth of relevant experiences are captured: 1) high-intensity outdoor enthusiasts (e.g., hikers, backpackers, campers, trail runners, bike riders), 2) low-intensity outdoor enthusiasts (e.g., gardeners, park walkers, etc.), 3) parents of children aged 5-10, and 4) parents of children aged 11-15. All focus groups will be conducted in English. A moderator guide (Attachment 3) will be used in all focus groups to facilitate a structured conversation around experiences, attitudes, behaviors, and reactions to the concepts and messages presented.

The data from this project is expected to provide valuable insights for the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID). Findings will be used to inform the potential development of a tailored outreach campaign (or campaign materials to disseminate to jurisdictions) aimed at raising awareness of Lyme disease and prevention steps among target populations. This data collection will help NCEZID refine its communication strategies and materials to better resonate with and motivate target audiences.

KRC Research, a contracted research firm, will conduct all data collection related to the proposed formative research project, under the supervision of NCEZID. KRC's data collection will include recruiting and screening participants into the project and conducting all eight online focus groups. Data collection is expected to be completed in August 2025.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected via online focus groups through a web-based platform, meaning that participants will not have to download anything to their personal devices (participants need only to have an internet connection). All focus groups will be conducted by professional moderators from KRC Research, a contracted company. All focus groups will be audio and video recorded to ensure participant responses are captured accurately and transcribed. Questions included on the moderator guide (Attachment 3) have been limited to only those relevant to the target audience to reduce burden on respondents.

4. Efforts to Identify Duplication and Use of Similar Information

While general research on Lyme disease prevention and health communication exists, this project focuses specifically on the formative testing of newly developed draft creative concepts and messages for NCEZID (Attachment 5). Evaluating the clarity, resonance, and impact of these unique materials requires new data collection directly from target audiences in high and emerging incidence states. Therefore, this information collection is necessary and does not duplicate previous efforts, as these specific communication materials have not been previously tested.

5. Impact on Small Businesses or Other Small Entities
No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently
The screeners and focus groups are all one-time information collections.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
There are no special circumstances with this information collection package. This request fully complies with the guidelines in 5 CFR 1320.5 and will be voluntary.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
A. This information collection request does not require publication of a 60-day notice in the *Federal Register*.

B. KRC Research, a contracted research firm, has been consulted in the development of the research plan, sampling parameters, and moderator guides. Under the supervision of NCEZID, KRC will ultimately conduct all data collection related to the proposed evaluation. Data collection will include recruiting and screening participants into the formative research and conducting eight 90-minute focus groups.

9. Explanation of Any Payment or Gift to Respondents
Participants will receive a monetary incentive of $75 for their participation. Such an incentive is a standard practice in the market research industry and helps to ensure efficient recruitment and ultimate participation among the qualified and scheduled participants. The amount is also standard for an audience participating in a focus group. The incentive is also intended to offset the cost of personal or professional time taken to participate.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents
NCEZID has determined that the Privacy Act does not apply to this information collection. KRC Research, a contracted firm, will manage recruitment and moderating for this initiative, and PII will not be transmitted to NCEZID or CDC.

The screening instrument for this evaluation is provided in Attachment 1. This screening instrument will be used to evaluate the qualification of potential participants. The screening instruments include information about privacy and confidentiality; only those individuals who agree to these terms will qualify for participation in focus groups. After an individual agrees to the terms and has qualified, they will be given a separate consent form (Attachment 2) that reiterates privacy and confidentiality policies. The participant will be required to sign the form (electronic submission is allowed) and deliver a copy to the recruiting and moderating team. The participant will be reminded that participation is entirely voluntary.

After the consent form is signed, participants will confirm their focus group slots. During the introduction to each discussion, the trained moderator will review key parts of the privacy and confidentiality agreement:

1. This discussion is completely voluntary. Participants may choose to leave the focus group and/or not answer a question at any time for any reason.
2. The evaluation team will take every precaution to protect participant identity and ensure privacy unless otherwise determined by law. This includes keeping names and answers to questions private and keeping contact information separate from any responses.
3. Results of the focus groups will be presented in aggregate, and names will not be used in any reports.
4. Discussions will be audio and video-recorded and notes will be taken during the discussion. All information, notes, and recordings will be locked in a file cabinet or a secure computer file. Only evaluation staff will be able to access the information.

No participants' personally identifiable information will be shared or made available to NCEZID. No recordings will be shared (audio or video), and shared transcripts will have names and any other identifiable information redacted. All findings will be reported in aggregate only.

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

Institutional Review Board (IRB)
This project was reviewed by NCEZID's human subjects advisor and determined to not meet the definition of research under 45 CFR 46. IRB review is not required (Attachment 4).

Justification for Sensitive Questions
All of the questions asked in the focus groups will be non-sensitive in nature and focus on individuals' knowledge and beliefs about Lyme disease and their reactions to creative concepts and messages. All participants will be informed that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer.

12. Estimates of Annualized Burden Hours and Costs
The total estimated burden is 154 hours. In sum, eight focus groups will be conducted. Table 1 below describes the burden associated with the information collection.

The burden table assumes that 10 respondents will be screened for every one successfully recruited and scheduled for a focus group. It also assumes that 8 individuals will be recruited for each focus group. (This one in ten rate is relatively high because sampling is conducted from within a panel of individuals already opted in surveys, focus groups, and interviews. Each individual also has a preexisting demographic profile that makes targeting recruitment much more efficient.) The burden table assumes screening will take 5 minutes per person, and the consent form will take an additional 5 minutes for those individuals who are successfully recruited. Focus groups last 90 minutes.

Table 1. Annualized Burden

Type of Respondent	**Form Name**	**No. of Respondents**	**No. of Responses per Respondent**	**Average Burden Per Response (hours)**	**Total Burden Hours**

U.S. Adults	Screener (Attachment 1)	640	1	5/60	53
	Consent Form (Attachment 2)	64	1	5/60	5
	Focus Group Guide (Attachment 3)	64	1	1.5	96
Total					154

According to the U.S. Bureau of Labor Statistics (BLS) May 2024 National Occupational Employment and Wage Estimates, the average hourly wage for all occupations is $32.66. This amount has been used to calculate the cost of participation for all respondents. The total estimated cost burden is $5,029.64.

Table 2. Cost burden associated with information collection

Type of Respondent	**Form Name**	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
U.S. Adults	Screener (Attachment 1)	53	$32.66	$1,730.98
	Consent Form (Attachment 2)	5	$32.66	$163.30
	Focus Group Guide (Attachment 3)	96	$32.66	$3,135.36
Total				$5,029.64

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers
There will be no direct costs to the respondents other than their time to participate in each information collection.

14. Annualized Cost to the Government
The annualized cost to the Federal Government to collect this information is $91,600.33. Table 3 below describes the cost in more detail.

Recruiting and data collection will be conducted by KRC Research, a contracted firm. KRC's work includes recruitment, screening, scheduling, management of consent forms, conducting focus groups, transcription and data cleaning, reporting, and presentation. Contractor costs cover the work of an existing team working with NCEZID on this and other communications initiatives. Contractor expenses are based on competitively bid prices for panel recruitment,

screening, and transcription, plus the cost of incentives. Contractor personnel costs are derived as follows: 24 hours for an EVP, 40 hours for a VP, 50 hours for a field director (recruitment activities), 50 hours for a research director, and 75 hours for an analyst.

Oversight and review of all materials and reports will be conducted by two federal government employees who are co-leading the project. Both are GS-14 health communication specialists. Their work will include providing oversight to KRC Research on the purpose and objectives of the project; guidance and feedback on recruitment, screening, and guide materials; entering the project materials into CDC's STARS system for project determination; meeting regularly with KRC Research staff to discuss the project's progress and answer any questions; reviewing the transcripts and reports; and sharing topline findings with NCEZID staff so they can use the findings to strengthen communication messages. The estimate includes 20 hours for Health communication specialist 1 and 24 hours for Health Communication Specialist 2.

Estimated federal employee cost is tabulated based on these two employees' current hourly wages (locality-adjusted GS pay table for Atlanta-area workers):

- Health Communication Specialist 1: 20 hours @ $76.56/hour = $1,531.20
- Health Communication Specialist 2: 24 hours @ $62.82/hour = $1,507.68
- Total = $3,038.88

Table 3. Estimated Annualized Cost to the Government per Activity

Cost Category	**Estimated Annualized Cost**
Contractor personnel costs: costs to oversee recruitment and conduct focus groups	$38,251.45
Contractor personnel costs: costs to report on results	$15,380.00
Contractor expenses: recruitment panel, transcription, incentives	$34,930.00
Federal government personnel costs: oversight, report review	$3,038.88
Total	$91,600.33

15. Explanation for Program Changes or Adjustments
This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule
This initiative is expected to take seven weeks from start to finish. Four weeks will be spent recruiting and conducting focus groups, and three weeks will be spent on analysis and reporting. A timeline is in Table 4.

Table 4. Project Time Schedule

Activity	Time Schedule
Recruit participants	2 weeks, beginning immediately after gen-IC approved (June 2025)
Conduct focus groups	2 weeks, overlapping with recruitment (8 focus groups)
Transcription, data processing, and analysis	1 week after focus groups end
Report development	2 weeks after analysis is complete
Disseminate results/reports	As soon as summary report is complete

Focus groups will be audio and video recorded for aid in reporting and analysis. Audio files will be transcribed verbatim in Microsoft Word and used for reporting. (Deidentified transcripts will be delivered to NCEZID.) Results will be used to develop one report with an assessment of findings and recommendations for refining creative concepts and messaging.

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

The expiration date of OMB approval will be displayed on all information collection instruments.

18. Exceptions to the Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.

List of Attachments

1. Screener
2. Consent Form
3. Focus Group Guide
4. Human Subjects Determination
5. Concept and Message Testing Stimuli