

**Community-based Tick Control for the Prevention of Rocky Mountain spotted fever in
Hermosillo, Mexico**

Request for OMB Approval of a New Information Collection

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Supporting Statement A

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Data Collection for Community-based tick control for the prevention of Rocky Mountain spotted fever in Hermosillo, Mexico

PART A. JUSTIFICATION

- Intended use of this information collection is to document enrollment and consent to participate in community based intervention, and to evaluate changes in knowledge, attitudes, and beliefs related to tick management before and after implementation of the tick management program in communities within Hermosillo, Mexico.
- The methods of information collection will include knowledge, attitude and practices (KAP) surveys carried out before and after the intervention to document changes in KAP, and household registration forms.
- The populations covered under this data request will include the general public in Hermosillo, Mexico.
- Data will be analyzed using statistical packages such as SAS®.

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Vector-Borne Diseases (DVBD), Rickettsial Zoonoses Branch (RZB), requests a 1-year approval of “Data collection for community-based tick control for the prevention of Rocky Mountain spotted fever in Hermosillo, Mexico.”

The broader project associated with the collection of data addressed in this request will provide evidence on the efficacy and impact of a community-based pilot project designed to reduce disease-carrying ticks in the home sites of participants. These activities include estimating the burden of tick infestation, monitoring and evaluating prevention and control activities, and assessing key knowledge and practices within the community in order to inform better educational practice.

The area in which the project is being conducted is suffering from high rates of the potentially deadly tickborne disease Rocky Mountain spotted fever (RMSF). Previous studies have shown the value in an integrated pest management plan to reduce the burden of ticks in the home environment and prevent RMSF. This project will constitute the first attempt at an integrated pest management plan to control ticks in the home sites of Mexican *poblados* (villages). The project will need to enroll households in the program and gather important contact information in the case of an emergency. The project will also need to have a basic understanding of the individual household risk. In order to monitor the impact of the intervention on tick populations and observe changes in knowledge, attitudes, and practices related to tick control and disease

prevention, it will be necessary to survey the participating populations both before and after the intervention.

The information collection for which approval is sought is in accordance with RZB's mission to reduce morbidity and mortality of rickettsial diseases and decrease the burden of disease through control and prevention methods.

Authorizing Legislation comes from Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment A).

2. Purpose and Use of Information Collection

The purpose of this data collection request is to allow the Rickettsial Zoonoses Branch to participate in the collection of information to monitor and evaluate a community-based tick prevention program led by the University of Sonora School of Medicine. The prevention project will have an intervention and a control community. The intervention will involve placing long lasting tick collars on all dogs in the community, providing routine acaricide treatment to the home and yard of registered participants, and providing education at every interaction with community residents and homeowners. Progress in the intervention community will be marked by routine evaluation of tick burden in the environment and on dogs. The intervention and control communities will both participate in knowledge, attitudes, and practices (KAP) surveys before and after the intervention, and results will be compared. The control community will receive education following each of the surveys, but tick control will be restricted to routine practices currently available throughout the state, which includes seasonal pesticide fogging (targeted towards mosquito prevention) and does not include provision of acaricidal products for dogs. The results of this pilot project will be used to inform Mexican health officials of the utility of integrated pest management practices for the prevention of Rocky Mountain spotted fever. Should the pilot intervention prove effective in this setting, activities may be expanded to include other highly impacted communities within Mexico. A pilot project is used to document efficacy and utility of an intervention on a small portion of the population to show proof of concept, before implementing on a larger scale. Assessing homeowner knowledge, attitudes, and practices relating to tick control and disease prevention will allow for the identification of current gaps and the development of targeted materials to improve the health and welfare of communities.

3. Use of Improved Information Technology and Burden Reduction

Whenever possible, RZB staff will employ electronic technology to collect and process data in order to reduce respondent burden and aid in data processing and reporting efficiency. Particular emphasis will be placed on compliance with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII.

Data collection will be conducted using paper forms and then entered into electronic databases to reduce the maintenance of paper resources and improve the security of information. Due to the rural location of data collection, electronic data collection will not be utilized. It is also felt that paper surveys may be more culturally appropriate and less invasive for community members.

The number of questions posed and number of repeat surveys will be held to the minimum required in order to elicit the necessary data.

4. Efforts to Identify Duplication and Use of Similar Information

Data collected under this data collection request is not expected to be duplicative or already in the possession of the federal government as similar projects in this environment have not yet been attempted. The results and final products from these activities may be used by multiple government and non-profit agencies within Mexico.

5. Impact on Small Businesses or Other Small Entities

Prevention and control activities are often undertaken in small, isolated communities where infrastructure may not be available for independent action. Research efforts will be carefully planned to minimize the burden on members of communities. All questions asked of individuals will be kept to a minimum, and the number of survey points will be reduced to only what is necessary to establish the efficacy of the program.

6. Consequences of Collecting the Information Less Frequently

It is necessary to measure the knowledge, attitudes, and practices and tick burdens prior to and following the program intervention in order to evaluate potential efficacy of the pilot tick prevention program. Fewer collections of data would not provide sufficient evidence to support or refute the efficacy of intervention and community buy in. Participants in the community will be enrolled once for the program prior to the start of the intervention. A sample of program participants and non-participants will be surveyed at two points: prior to and following the program intervention.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The activities outlined in this package fully comply with all guidelines of 5 CFR 1320.5.

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

8a. A 60-day Federal Register notice was published in the Federal Register on November 10, 2015, Vol. 80, No. 217, pg. 69680-69681 (Attachment B). One non-substantive comment was received (Attachment G) and CDC's standard response was sent.

8b. Consultation

Data collection types and methods required for this OMB clearance have been developed in collaboration with the University of Sonora School of Medicine to provide locally appropriate questions, clarity of instructions, frequency of solicitation and reporting practices associated with this data collection. Consultation was led through a faculty member with the University of Sonora School of Medicine, Dr. Gerardo Alvarez Hernandez (galvarezh63@gmail.com) in 2014 and 2015. No problems were identified during the period of consultation.

9. Explanation of Any Payment or Gift to Respondents

There will be no remuneration to respondents of the general public for participation in the pilot project, however participants in the intervention area will receive long lasting tick collars for all dogs, routine acaricide treatments for their home and yard, and educational materials. Control communities will receive routine care provided by the state, which currently involves seasonal acaricide fogging (targeting mosquitos) and will receive educational materials following participation in the KAP survey. Individuals and households will not be remunerated for participation in the survey itself. It is not expected that questions posed as part of this data collection will constitute a significant burden on survey respondents. Similar projects conducted in Arizona were successfully enacted without remuneration while achieving the desired sample size and participation.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

Individuals and organizations will be assured of the privacy of their replies under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c). They will be told the purposes for which the information is collected and that, in accordance with this statute, any identifiable information about them will not be used or disclosed for any other purpose without their prior consent, unless required by law upon the demand of a court or other governmental authority.

Local or State public health officials with jurisdictional responsibility will maintain the respondent's name, telephone number, and other personally identifiable information. No identifying information will be transmitted to CDC. Whenever possible, data will be collected anonymously to ensure the privacy of survey response.

RZB staff will follow procedures for assuring and maintaining privacy during all stages of data collection. All information provided by respondents will be treated in a secure manner and will not be disclosed unless otherwise compelled by law. IRB approval was granted prior to commencement of any activities. The IRB application outlines the details regarding data collection, storage and use.

Privacy Impact Assessment Information

RZB staff will follow procedures for assuring and maintaining privacy during all stages of data collection. Individually identifiable information will be collected for enrollment into the project due to the application of chemical products to the home environment and to domestic animals living on the home site. In order to establish homeowner permission to use these products and for staff to gain access to home sites without the homeowner present, informed consent will be obtained prior to the start of intervention (Attachment E). The proposed data collection will likely have little or no effect on respondents' privacy. All information provided by respondents will be treated in a secure manner and will not be disclosed unless otherwise compelled by law. Respondents will be informed prior to participation that their responses will be treated in a secure manner.

Information in identifiable form (IIF) will be collected on household registration forms only from homes participating in the intervention. These data will include the homeowner name, address, and contact information including telephone number. These data will be collected on paper forms, secured in locked cabinets by the local health department or the University of Sonora School of Medicine, and will only be referenced in case of an emergency. RZB will not receive any IIF. Participants will be informed of the purpose of the collected information and that information disclosure is mandatory for participation in the project and the home owner can either consent to provide the information or refuse and not be enrolled in the project. Household registration will be maintained for 6 months following the end of program activities and will then be destroyed.

Non-identifiable data will be collected through pre and post surveys of participating households and non-participating households. These surveys will be obtained anonymously and will not be tied to location outside of neighborhood. Survey responses will not be tied to individual respondents. Data collected in pre and post surveys may include questions about knowledge, attitudes, and practices regarding tick control and disease prevention. Non-identifiable information will be maintained in paper format for up to three years following the completion of the project and will remain the property of the University of Sonora School of Medicine.

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

Institutional Review Board (IRB)

The CDC IRB approved the request to rely on the IRB of the University of Sonora School of Medicine. The protocol was reviewed in December 2015, and approval was granted (Attachment F). Prior to participating in the information collection, prospective respondents will receive information regarding the nature of the data collection activity. A staff member will address any questions the participants have about the project prior to data collection. RZB staff will assist with the collection and analysis of research data led by the University of Sonora.

Justification for Sensitive Questions

The majority of questions asked will not be of a sensitive nature. However, some respondents may find thinking about and discussing a disease unpleasant, especially members of the general public who have suffered a loss caused by rickettsial disease. A portion of respondents could consider questions about race, ethnicity, or other demographic characteristics to be sensitive, although such questions are unlikely to be highly sensitive. Where relevant to the information collection, race and ethnicity data will be collected consistent with HHS policy and standard OMB classifications.

Additionally, some respondents may feel uncomfortable answering particular questions about their individual experiences, level of disease awareness, and/or adopted preventative behaviors (or lack thereof) associated with various diseases. To minimize psychological distress, the moderator or data collection instrument instructions will inform participants that they do not have to respond to any questions they do not want to answer and they may stop participating at any time. In addition, a subject matter expert from RZB will be present during the information collection to answer questions from participants at the end of the information collection activity.

12. Estimates of Annualized Burden Hours and Costs

A. The average burden for each respondent depending on the specific data collection and type of respondent is 10-20 minutes depending on the information collection type. Based on community population surveys in the target intervention area and sample size justifications for it, it is estimated that approximately 1,300 general public respondents may participate in data collection efforts relating to this data collection request (500 registrations obtained at one time only and 800 KAP surveys (400 in the control community and 400 in the intervention community) obtained at two points in time (the pre and post survey). Although average response times are only 10-20 minutes, some individuals may take longer to provide the requested data, however the total burden on respondents will not exceed a combined burden hours of 700 hours annually.

Data regarding average annual income for local participants were not available. The 2013 mean average hourly wage for all occupations in the United States was used. However, this is likely an over estimation based on local observations of low socioeconomic status in the target intervention area. The US wage of \$22.33 was obtained from the Bureau of Labor Statistics (http://www.bls.gov/oes/current/oes_nat.htm). Burden in hours is taken from Table 12-A. The total annual cost burden is calculated by multiplying the mean hourly wage by the burden in hours. The total cost burden is estimated to be \$15,653.33.

The estimated burden to respondents is summarized in Table 12-A below.

Table 12-A: Estimated Annualized Burden to Respondents

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
General Public	Registration (Attachment C)	500	1	20/60	167
General Public	KAP survey (pre and post intervention) (Attachment D)	800 (400 control and 400 intervention)	2 (pre and post intervention)	20/60	533
Total					700

There are no costs to respondents except their time to participate in the research activities. The total annualized burden to respondents is 700 hours.

Table 12-B: Estimated Annualized Cost to Respondents

Type of	Form Name	Total Burden	Hourly Wage Rate	Total Respondent Costs
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respondents		Hours		
General public	Registration (Attachment C)	167	\$22.33	\$3,729.11
General Public	KAP survey (pre and post intervention) (Attachment D)	533	\$22.33	\$11,901.89
Total				\$15,631.00

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

None.

14. Annualized Cost to the Government

The estimated average annual cost to the federal government for the proposed information collection activities is \$83,500. This figure encompasses 50% FTE of two GS-13 employees and ancillary information collection costs. The average hourly rate was obtained from the Office of Personnel Management’s website (http://www.opm.gov/oca/09tables/html/atl_h.asp). The hourly rate for a GS-13 in metro Atlanta is \$40.11 per hour, which is about \$83,500 per year.

Table 14-A: Estimated Annualized Cost to the Government

Estimated Annualized Cost to the Government per Activity and Total	
Cost Category	Total Estimated Annualized Cost
Federal employee costs, per information collection (50% FTE of two GS-13 at \$83,500/year)	\$83,500

15. Explanation for Program Changes or Adjustments

This is new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Project Time Schedule

It is unknown at this time whether the results from this information collection will be published. A report based on the results will be generated, but publication determination will be the decision of the University of Sonora School of Medicine.

Table 16.1

Project Time Schedule	
<i>Activity</i>	<i>Time schedule</i>
Household registration	1 month after OMB approval
Data collection	2-10 months after OMB approval
Data analysis	10-11 months after OMB approval
Generation of report	12 months after OMB approval

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

None.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Not applicable. No certification exemption is being sought.

Attachments

- A. Public Health Service (PHS) Act (42 USC 241).
- B. 60-Day Federal Register Notice
- C. Household registration form for participation in the community based tick prevention project
- D. Knowledge, attitudes, and practices survey of households
- E. Consent letter
- F. IRB approval letter
- G. Public comment