

Canine Leptospirosis Surveillance in Puerto Rico

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Supporting Statement A

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Canine Leptospirosis Surveillance in Puerto Rico

- The goals of the data collection are to characterize the epidemiology of canine leptospirosis in Puerto Rico, assess the applicability of canine *Leptospira* vaccines used in the island, and determine potential rodent, livestock, and wildlife reservoirs for leptospirosis. Findings from the study will be used to develop recommendations for the prevention of leptospirosis in dogs, focus human surveillance efforts, and guide further investigations on leptospirosis in Puerto Rico.
- The populations covered under this data request include veterinarians and staff from participating veterinary clinics and shelters (sites) and owners of enrolled dogs. Dogs with febrile illness that present to participating sites and meet the case definition will be enrolled in the surveillance project. Enrolled dogs will have an on-site leptospirosis

Zoonotic Infectious Diseases (NCEZID), Division of High-Consequence Pathogens and Pathology (DHCPP), Bacterial Special Pathogens Branch (BSPB), requests three years of OMB approval for a reinstatement ICR.

1. Circumstances Making the Collection of Information Necessary

Leptospirosis, a disease in humans and animals, is transmitted through contact with the urine of infected animals, either directly or through exposure to contaminated water or soil. In dogs, the disease can present as an acute febrile illness. The often non-specific symptoms, as well as a wide range of clinical presentations can make it difficult to diagnose. Early diagnosis can result in rapid initiation of treatment and improve chances of survival in affected canines, as well as decrease the risk of infected dogs shedding leptospire into the environment and providing a potential source for human infection. Barriers to determining the actual burden of canine leptospirosis in Puerto Rico as well as the circulating leptospirosis serovars include the unavailability of diagnostic testing on the island and the lack of a veterinary surveillance system to detect and report cases.

Leptospirosis is endemic in Puerto Rico, however, there is very limited data on canine leptospirosis in the island. In 1980, Farrington and Sulzer¹ did a serosurvey of antibodies to *Leptospira* in 116 stray dogs at three shelters in the island. In 1998, an unpublished serosurvey of *Leptospira* antibodies in stray and companion dogs found seropositivity in a third of dogs sampled.² Since then, no study has been done on leptospirosis in dogs. Human cases of leptospirosis became nationally notifiable in 2013 and CDC began receiving case notifications in 2014. About half of the cases reported to CDC through the National Notifiable Diseases Surveillance System (NNDSS) (OMB Number 0920-0728) in 2014 and 2015 were reported by Puerto Rico.³

In Puerto Rico, many owned dogs and shelter dogs are not vaccinated against leptospirosis. Annual vaccination is recommended by the American Veterinary Medical Association for at-risk dogs.

The project associated with the collection of data addressed in this request aims to establish the first active surveillance for canine leptospirosis in Puerto Rico in order to learn more about canine leptospirosis, as well as leptospirosis in general, on the island. The information collection for which approval is sought is in accordance with BSPB's mission to prevent illness, disability, or death caused by bacterial zoonotic diseases through surveillance, epidemic investigations, epidemiologic and laboratory research, training and public education.

¹ Farrington, N. P. and K. R. Sulzer (1982). "Canine leptospirosis in Puerto Rico." *Int J Zoonoses* 9(1): 45-50.

² Torres, et. al. "Canine Leptospirosis in Puerto Rico." Unpublished study, Tuskegee University College of Veterinary Medicine, Nursing, and Allied Health, 1998.

³ National Notifiable Diseases Surveillance System. Centers for Disease Control and Prevention. Atlanta, GA. Accessed on August 3, 2016.

As of November 2018, there are 104 dogs enrolled in the surveillance project. The total enrollment is well below the desired minimum sample size of 385 dogs. Enrollment during the first year of the project was slow as participating veterinary facilities were learning and becoming familiar with the surveillance protocol. After Hurricanes Maria and Irma made landfall in Puerto Rico in September 2017, most veterinary facilities were closed for months. In the following months post-hurricane, canine leptospirosis surveillance, unfortunately, stopped as the sites recovered from the disaster. However, there were several anecdotal reports from participating veterinarians observing an increase in suspect leptospirosis cases.

PRDH and the CDC also documented an increase in human leptospirosis cases post-hurricanes. Due to this, there are increased efforts to enhance surveillance in Puerto Rico and better understand leptospirosis in humans, animals, and the environment to inform prevention and response activities. The canine leptospirosis surveillance project is an important part of leptospirosis surveillance. The information provided from this project helps to inform animal public health and complements the One Health leptospirosis activities developing in Puerto Rico.

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 information collection request is to determine the incidence and distribution of canine leptospirosis in Puerto Rico; assess risk factors that lead to infection; characterize circulating *Leptospira* serovars and species; assess applicability of vaccines currently in use based on serovar determination; and assess potential rodent, livestock and wildlife reservoirs of leptospirosis based on infecting serovars found in dogs.

Using the One Health concept (incorporating human, animal, and environmental health) for the control and prevention of leptospirosis, findings from the canine leptospirosis surveillance study will be used to develop evidence-based, targeted interventions and recommendations for the prevention of canine leptospirosis which can also lead to reduced leptospirosis transmission in humans, focus human surveillance efforts based on incidence and distribution, and guide future investigations into leptospirosis in humans and animals.

The surveillance project was first conceived of by the Puerto Rico Department of Health (PRDH) in 2011 and BSPB's assistance was requested. BSPB provided assistance including protocol development and data collection tool development in conjunction with the PRDH project collaborators, confirmatory leptospirosis diagnostic testing at CDC, and data entry of collected surveillance data as PRDH then lacked the staff time for these activities.

However, due to shifting priorities at PRDH, BSPB has decided to continue the project and is now collaborating with the Puerto Rico Veterinary Medical Association (PRVMA). BSPB continues to manage the day-to-day operations of the project and holds ownership of the data. The PRVMA provides support with communications and training-related activities for veterinary facilities participating in canine leptospirosis surveillance in Puerto Rico. Summary reports may be shared periodically with all collaborators.

In the next two years, several leptospirosis surveillance and research activities in humans, animals and the environment will be developed in Puerto Rico by the CDC and other federal and non-government agencies. The approval of this reinstatement and continuation of information collection for canine leptospirosis will contribute to this One Health understanding of leptospirosis in Puerto Rico.

3. Use of Improved Information Technology and Burden Reduction

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

Due to the nature of data collection and resources available at the sites, most of the data collection will be conducted using paper forms. Veterinarians and their staff may find it easier to complete a paper copy of the data collection forms when abstracting information from medical records or while interviewing the owner for risk factors and symptoms. Some sites may have limited resources and lack a computer, fax machine, or internet service. As such, they have the option of sending completed forms by fax or email, or by mail when sending specimen shipments to study coordinators at CDC or PRDH. Data will be entered into an electronic database at CDC to make data management and analysis more efficient.

4. Efforts to Identify Duplication and Use of Similar Information

A literature search of published articles on canine leptospirosis in Puerto Rico was performed and very few articles were found. Two of the most relevant articles found were serosurveys from 1980 and 1998, in which information collected may already be outdated. In addition, collaborators at PRDH were consulted to identify duplication of information collection and to ensure that information collected is relevant and useful for public health activities in Puerto Rico. Finally, active surveillance for canine leptospirosis has not been done before in Puerto Rico, thus, duplication of data collection is not expected.

5. Impact on Small Businesses or Other Small Entities

The study may collect information from small veterinary clinics and shelters. The proposed information collection tool contains the minimum amount of information needed to meet the goals of the study. There is no cost associated with the information collection to the sites other than the time used by the veterinarian and their staff to complete the data collection tool. All supplies for the study are provided, including paper copies of data collection tools if the site requests this. As such, the impact on small businesses is expected to be minimal.

6. Consequences of Collecting the Information Less Frequently

Informal interviews with local veterinarians in Puerto Rico found an average of two cases of leptospirosis per month in dogs seen at the clinics, with some variance depending on the site location. As such, the sample size is projected to be relatively small and each response would be needed to obtain significant data and results. There is very limited data on canine leptospirosis in

Puerto Rico, and what is known may be outdated. There is also no system of veterinary surveillance in the island and rapid diagnostic tests for leptospirosis are not widely used. These factors have held back further understanding of the incidence and distribution of leptospirosis in dogs. Thus, this data collection would be the primary source of information on canine leptospirosis in Puerto Rico.

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

Study sites are asked to send completed data collection forms at least monthly to coordinate with the shipment of specimens for additional testing at CDC. This is because there is information in the data collection forms that may be used to guide the interpretation of test results and to keep track of specimens that are sent.

All other activities outlined in this package fully comply with the 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 notice was published in the Federal Register on January 29, 2019, Vol. 84, No. 19, p. 457-458. (Attachment B). No public comments were received.

8b. Consultation

Data collection types and methods required for this OMB clearance have been developed in consultation with Brenda Garcia-Rivera, previous territorial epidemiologist for Puerto Rico, and Kyle Ryff, previous surveillance coordinator with the Division of Epidemiologic Investigation at Puerto Rico Department of Health. Their consult was obtained to determine efficient ways of data collection and submission, and to ensure the use of locally appropriate questions and instructions associated with this data collection. Issues or improvements to the data collection tool as a result of their consult were addressed prior to its implementation.

9. Explanation of Any Payment or Gift to Respondents

There will be no remuneration to any of the respondents (veterinarians and their staff, and dog owners) for the data collection associated with the study. Only supplies for the study will be provided, including paper copies of data collection tools, and supplies for specimen collection, testing and shipment. Owners of enrolled dogs may also be provided with an informational brochure on leptospirosis.

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

NCEZID reviewed this submission and determined that the Privacy Act does apply. The applicable SORN is 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems."

Individuals will be assured of the security of the information they provide through a consent form. They will be told the purposes for which the information is collected and that any information they provide will be kept secure to the extent permitted by law. Any personal

identifiable information collected will be stored in a secure manner and will not be disclosed unless otherwise compelled by law.

A determination from the Institutional Animal Care and Use Committee (IACUC) specialists at CDC was sought prior to commencement of any activities. The protocol associated with this study was determined to be exempt from IACUC review. IRB determination was not pursued as this study does not pertain to research on human subjects.

Privacy Impact Assessment Information

BSPB staff will follow procedures for assuring and maintaining the security of information collected. Information collected from participating sites such as clinic name, address, capacity for dogs, and services offered, will be used only for the purposes of the study, unless authorized by the clinic or shelter. Information about the dog will be collected by veterinarians and their vet staff according to the facility's protocol. The type of information collected will pose minimal to no risk to respondents. Owner and dog identifiable information, including the dog owner's last name and address, and the dog's name will be used for study purposes and only authorized staff from CDC and PRVMA will have access to this information. The database and scanned copies of completed forms will be stored in a secure CDC server. Hardcopy forms will be stored in a locked cabinet in a secure CDC facility with controlled access.

A Privacy Impact Assessment is included with this submission (Attachment I).

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

Institutional Review Board (IRB)

This study does not conduct research on human subjects. As such, IRB approval was not sought. Instead, a determination for IACUC protocol review was pursued with CDC Atlanta IACUC contacts – Kristin Mayfield (erv@cdc.gov) and Linda Capewell Pimentel (gsu2@cdc.gov). In February 2016, this study was determined to be exempt from IACUC review (Attachment G).

Justification for Sensitive Questions

All questions pertain to the dog and not the owner with the exception of the owner's last name and address. No sensitive questions are asked in the data collection tools.

12. Estimates of Annualized Burden Hours and Costs

There is no change to the estimated annual time burden in this reinstatement.

A. The burden to respondents depending on the type of respondent and form is estimated to be 1-10 minutes. There is little known regarding the prevalence of leptospirosis in dogs in Puerto Rico, and therefore a sample size of at least 385 dogs was determined based on a population estimate of 150,000-300,000 dogs by the Humane Society of Puerto Rico (unpublished data), a 95% confidence level with a 5% margin of error, and a prevalence of 50% which is the estimated prevalence of leptospirosis in dogs giving the largest sample size.

In Table 12-A below, the total annualized burden for the information collection is summarized by type of respondent and form. The enrollment questionnaire is completed once in the beginning of the study while the log sheet and case questionnaire will be completed for each enrolled suspect case. The number of suspect cases can vary from 0 to 2 cases per month depending on the location of the clinic/shelter based on anecdotal reports from local veterinarians. Taking the highest possible response per month, the number of responses per form for the log sheet and case questionnaire is calculated by multiplying 2 cases/month with 12 months giving a total of 24 responses per form for each veterinarian. The total number of veterinarians is not expected to exceed 26 (the maximum number of participating sites).

A minimum of 385 responses from dog owners is needed based on sample size calculation. However, extra clinics were enrolled to ensure that the sample size is met in the event that some clinics withdraw from the study or if fewer numbers of suspect leptospirosis cases are enrolled at the clinics. Given this, a maximum of 624 responses (26 clinics x 24 responses/clinic) is calculated for the burden to the general public (dog owners). Although it is unlikely the maximum number of responses will be reached, the total number of dog owners will not exceed 624. There are no costs to respondents except their time to participate in the research activities.

As of November 2018, there are 104 dogs enrolled in the surveillance project.

The total annualized burden to respondents is 168 hours.

Table 12-A: Estimated Annualized Burden to Respondents

Type or Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hours)	Total Burden (in hours)
Veterinarian	Enrollment Questionnaire (Attachment C)	26	1	5/60	2
	Log Sheet (Attachment D)	26	24	1/60	10
	Case Questionnaire (Attachment E)	26	24	10/60	104
General Public (Dog owner)	Case Questionnaire (Attachment E)	624	1	5/60	52
Total					168

B. To estimate the cost to respondents, we used the May 2017 State Occupational Employment and Wage Estimate for Puerto Rico obtained from the Bureau of Labor Statistics (http://www.bls.gov/oes/current/oes_pr.htm). Since either the veterinarian or their veterinary staff may complete the data collection tools, we took the average of their mean hourly wages (\$43.95 for veterinarians; and \$14.70 for veterinary technologists and technicians) to calculate the hourly wage rate of \$29.33. The mean hourly wage for all occupations for the general public is \$13.91. The total annual cost burden is calculated by multiplying the mean hourly wage by the burden in hours. The total cost burden to respondents is estimated to be \$4,125.60.

Table 12-B: Estimated Annualized Cost to Respondents

Type of respondents	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Veterinarians or Vet Staff	Enrollment Questionnaire (Attachment C)	2	\$29.33	\$58.66
	Log Sheet (Attachment D)	10	\$29.33	\$293.30
	Case Questionnaire (Attachment E)	104	\$29.33	\$3,050.32
General Public	Case Questionnaire (Attachment E)	52	\$13.91	\$723.32
Total				\$4,125.60

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 \$75,105. This figure includes the cost of supplies for specimen collection, testing and shipment to CDC; the cost of one contract employee (20% of an epidemiology fellow equivalent to a GS-9 employee); and three federal employees (10% of a GS-9 Civilian Employee and 5% of two Commissioned Corps with ranks equivalent to GS-13 employees).

The average hourly rate of a federal employee in Atlanta was obtained from the 2018 GS Pay Tables from the Office of Personnel Management's website (<https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/>). The hourly rate for a GS-9 level employee is \$25.46 which

is equivalent to \$53,137 annually. The hourly rate for a GS-13 level employee is \$43.91, equivalent to \$91,631 annually.

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
Cost of supplies for specimen collection, testing, and shipment to CDC	\$50,000
10% of one GS-9 Civilian Employee (epidemiologist) at \$53,137/year	\$5,314
5% of one Commissioned Corp (microbiologist) equivalent to a GS-13 employee at \$91,631/year	\$4,582
5% of one Commissioned Corp (epidemiologist) equivalent to a GS-13 employee at \$91,631/year	\$4,582
20% of one contract employee (epidemiology fellow) equivalent to a GS-9 employee at \$53,137/year	\$10,627
Total Cost	\$75,105

15. Explanation for Program Changes or Adjustments

This is a request for reinstatement of a formerly approved information collection in use. Changes were recently made to the protocol to try to simplify the dog enrollment, specimen collection and culture inoculation processes, and to reduce the time burden to respondents. Protocol changes include simplification of the suspect case clinical criteria, standardization of the process for selecting diagnostic samples to be shipped to CDC, and removal of culture inoculation for whole blood and urine specimens. As a result, minor revisions were made to the data collection tools to reflect changes in the protocol. Revisions include:

1. Log Sheet (Attachment D)
 - a. Removal of check boxes for Blood Culture and Urine Culture
2. Case Questionnaire (Attachment E)
 - a. Changed wording from “Clinic/Shelter Patient ID” to “Clinic/Shelter Patient Record ID.” to reduce confusion
 - b. Added a question to capture test results of the Zoetis WITNESS lepto test only if the clinic performs the test as part of their routine protocol
 - c. Stated the option to send a copy of routine lab hematology, biochemistry and urinalysis reports if the tests are performed instead of filling in lab results in the questionnaire.
 - d. Changed the title of the section “Outcome” to “Hospitalization Status and Outcome”
3. Owner Consent Form (Attachment F)
 - a. Simplified the wording in paragraph 2 and updated to reflect changes in specimen collection criteria.

4. Kidney Consent Form (Attachment H)
 - a. New document developed to obtain separate consent from owners to collect a kidney sample from enrolled dogs, if euthanized.
5. Privacy Impact Assessment (Attachment I)
 - a. In accordance with CDC requirements, a Privacy Impact Assessment was completed and signed for this project.

16. Plans for Tabulation and Publication and Project Time Schedule

A report based on study results will be generated and the findings used to develop recommendations to prevent leptospirosis in dogs in Puerto Rico. This report will be shared with all study collaborators. Results from this information collection may be published in collaboration with the PRVMA and participating veterinary facilities.

Project Time Schedule

Training of 8 participating sites and subsequent information collection from the trained sites began during a site visit in June 2016. Training of the remainder of the sites will be conducted at a rolling basis due to limitations in staff availability. Additional training sessions may be conducted as needed or if requested by participating sites. Data collection at each site is expected to continue for at least a year or until a sample size of at least 385 dogs has been met, after which the study may be continued based on study outcome during the first year and if all participants and investigators are in agreement. As of November 2018, there are 104 dogs enrolled in the surveillance project. The total enrollment is well below the desired minimum sample size of 385 dogs. As such, an additional 3-year approval for this information collection is requested to ensure that the sample size is met and meaningful information is collected.

Table 16-A: Project Time Schedule

Project Time Schedule	
<i>Activity</i>	<i>Time schedule</i>
Initial site enrollment and training; refresher training may be given as needed	June 2016 - February 2017
Data collection	June 2016 – June 2021
Data analysis	3-7 months after the end of data collection
Generation of report	8-12 months after the end of data collection

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. Site Enrollment Questionnaire
- D. Study Log Sheet
- E. Case Questionnaire
- F. Owner Consent Form
- G. IACUC Exemption
- H. **Kidney Consent Form**
- I. **Privacy Impact Assessment**