

BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-19-1170; Docket No. CDC-2018-0113]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the data collection project titled "Canine leptospirosis surveillance in Puerto Rico." This surveillance project aims to characterize the epidemiology of canine leptospirosis, assess the applicability of canine *Leptospira* vaccines used in Puerto Rico, 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.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2018-0113 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Canine Leptospirosis Surveillance in Puerto Rico (OMB Control No. 0920-1170 Exp. Date 03/31/2019) - Revision - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) Bacterial Special Pathogens Branch (BSPB) requests for approval of revisions to existing data collection tools used in active surveillance for canine leptospirosis in Puerto Rico. The methods for data collection have not changed.

Active surveillance allows for the collection of prospective data on acute cases to determine the incidence and distribution of leptospirosis in dogs, assess risk factors for infection, characterize circulating *Leptospira* serovars and

species, assess applicability of vaccines currently in use based on serovar determination, and assess rodent, livestock, and wildlife reservoirs of leptospirosis based on infecting serovars found in dogs. Findings from this study will aid in the development of evidence-based, targeted interventions for the prevention of canine leptospirosis, be used to focus human leptospirosis surveillance efforts, and guide future investigations on leptospirosis in humans and animals in Puerto Rico.

The information collection for which approval 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. Authorizing Legislation comes from Section 301 of the Public Health Service Act (42 U.S.C. 241). Successful execution of BSPB's public health mission requires data collection activities in collaboration with the state health department in Puerto Rico and with local veterinary clinics and animal shelters participating in the study.

These activities include collecting information about dogs that meet the study case definition for a suspect case of leptospirosis seen at participating veterinary clinics and shelters. Participating veterinarians and their veterinary staff

collect information by interviewing the dog owner (shelters are an exception as dog will not have an owner) and reviewing medical and administrative records, as necessary. Basic information about the participating sites will also be collected for study management and to enhance data analysis.

Information will be collected using paper forms and provided in Spanish. Staff at participating sites find it easier to complete a paper copy when abstracting medical record information and interviewing owners for information about their dog's risk factors and symptoms. Study coordinators will enter collected data into an electronic database.

The types of information collected include information about the dog's signalment, location of residence, environmental risk factors, vaccination history, clinical signs and symptoms, laboratory results, and clinical outcome. Approval of this revision ICR will allow BSPB to continue to collect information which can help inform animal public health and will help contribute to a One Health understanding of leptospirosis in Puerto Rico.

BSPB estimates involvement of at least 411 respondents (a minimum 385 from the general public and 26 veterinarians and their veterinary staff) and estimates a total of 168 hours of burden for research activities each year. The collected information will not impose a cost burden on the respondents

beyond that associated with their time to provide the required data.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Veterinarians or veterinary staff	Enrollment Questionnaire (Attachment C)	26	1	5/60	2
Veterinarians or veterinary staff	Log Sheet (Attachment D)	26	24	1/60	10
Veterinarians or veterinary staff	Case Questionnaire (Attachment E)	26	24	10/60	104
Dog owners (general public)	Case Questionnaire (Attachment E)	624	1	5/60	52
Total					168

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 Information Collection Review Office,
 Office of Scientific Integrity,
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