ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Individuals	Standardized National Hypothesis Generating Questionnaire (Core Elements).	4,000	1	45/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–17–16BGH; Docket No. CDC–2016–0097]

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 efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on data collection project entitled ''Data Collection for Canine Leptospirosis Surveillance in Puerto Rico.'' The goals of the project are 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: Written comments must be received on or before December 12, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2016–0097 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov.*

Please note: All public comment should be submitted 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 the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *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 OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

''Data Collection for Canine Leptospirosis Surveillance in Puerto Rico''—Existing Collection in Use without an OMB Control Number—National Center for Emerging and Zoonotic 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 approval of data collection tools to be used for active surveillance of canine leptospirosis in Puerto Rico. Active surveillance will allow 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 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. 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. The information is collected by veterinarians or their veterinary technical staff by interviewing the dog owner and reviewing medical and administrative records, as necessary. Basic information about the participating sites will also be collected for study management, as well as to augment data analysis.

Approval of this data collection tool will allow BSPB to collect information from veterinarians, vet staff and dog owners about the dog's signalment, risk factors, clinical signs and symptoms, laboratory results, treatment, and outcome. The study will also collect basic site information from participating clinics and shelters, including information about site capacity, vaccination practices, origin of dogs, and resources available at the sites.

Data collection tools will be completed onsite. For dogs that have an owner, information about the dog may be collected by veterinarians and their vet staff by interviewing the dog owner. Otherwise, data collection tools may be completed by reviewing administrative and medical records, as necessary. Data will be recorded on paper forms. Study coordinators will enter collected data into an electronic database.

BSPB estimates involvement of at least 411 respondents (385 from the general public and 26 veterinarians and their veterinary technical 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 vet technical staff	Enrollment Questionnaire	26	1	5/60	2
Veterinarians or vet technical staff	Log Sheet	26	24	1/60	10
Veterinarians or vet technical staff	Case Questionnaire	26	24	15/60	156
Total					168

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Times and Dates:

8:30 a.m.–5 p.m., EDT, November 2, 2016.

8:30 a.m.–12 p.m., EDT, November 3, 2016.

Place: CDC, 1600 Clifton Road NE., Tom Harkin Global Communications Center, Building 19, Auditorium B, Atlanta, Georgia 30329.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people. This meeting will also be webcast, please see information below.

Purpose: This Committee is charged with providing scientific and technical advice and guidance to the Secretary of Health and Human Services (HHS); the Assistant Secretary for Health; the Director, Centers for Disease Control and Prevention; the Commissioner, Food and Drug Administration (FDA); and the Administrator, Centers for Medicare and Medicaid Services (CMS). The advice and guidance pertain to general issues related to improvement in clinical laboratory quality and laboratory medicine practice and specific questions related to possible revision of the Clinical Laboratory Improvement Amendment (CLIA) standards. Examples include providing guidance on studies designed to improve safety, effectiveness, efficiency, timeliness, equity, and patient-centeredness of laboratory services; revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards on medical and laboratory practice; and the modification of the standards and provision of non-regulatory guidelines to accommodate technological advances, such as new test methods, the electronic transmission of laboratory information, and mechanisms to improve the integration of public health and clinical laboratory practices.

Matters for Discussion: The agenda will include agency updates from CDC, CMS, and FDA. Presentations and discussions will include a report on the cytology workload assessment and time measure study; an update on CLIAC recommendations for laboratory biosafety; laboratory preparedness and response: The case of Zika; a report from the Institute of Medicine (IOM) CLIAC workgroup; and future CLIAC topics.

Agenda items are subject to change as priorities dictate.

Webcast: The meeting will also be webcast. Persons interested in viewing