

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.

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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

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 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 CLIA recommendations for laboratory biosafety; laboratory preparedness and response: The case of Zika; a report from the Institute of Medicine (IOM) CLIA workgroup; and future CLIA topics.

Agenda items are subject to change as priorities dictate.

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