

industry using PFAS chemicals in its manufacturing process). Likewise, children whose birth mothers were occupationally exposed will not be eligible. ATSDR assumes that 5 percent of the people who volunteer will not meet eligibility requirements; therefore, a total of 8,400 people will be screened. To complete the data collection in three years, annualized estimates for eligibility screening are 2,800 people (2,100 adults and 700 children) and an annual time burden of 467 hours. The recipients will provide appointment reminder calls for each eligible person who agrees to be enrolled (n = 2,667 per year) for a time burden of 222 hours per year.

At enrollment, each recipient will obtain adult consent, parental permission, and child assent before data collection begins. For each participant, the recipient will take body measures, collect blood samples to measure PFAS serum levels and several effect biomarkers such as lipids, and thyroid, kidney, immune and liver function. The recipient will also obtain urine samples from participants to measure PFAS levels and kidney function biomarkers.

The study will archive leftover serum and urine samples for additional analyses of PFAS chemicals and specific effect biomarkers. The National Center for Environmental Health (NCEH) laboratory will perform blood and urine PFAS analyses for all Multi-site Study participants. Thus, issues of inter-laboratory variability for exposure measures will be eliminated.

Adult participants and a parent of child participants will complete a questionnaire that includes residential history, medical history, occupational history, and water consumption habits (n=2,000 adults and 667 children per year). Ideally, the parent will be the child's birth mother, as ATSDR will ask details about the child's exposure, pregnancy, and breastfeeding history.

For purposes of time burden estimation, ATSDR assumes that 20 percent of parents will also enroll as adults and can take the child short form questionnaire (n=133 per year); therefore, 534 parents will take the child long form questionnaire per year. Parents and children, with administration by trained professionals, will also complete neurobehavioral

assessments of the child's attention and behaviors (n=667 per year).

To facilitate access to medical and school records, each recipient will reach out to local medical societies, public school systems, and private schools, to enlist their cooperation with the study. The recipient will ask for permission to abstract participants' medical records to confirm self-reported health outcomes. The recipient will also seek permission to abstract and compare children's school records to their behavioral assessment results. Based on ATSDR's experience from the Pease proof of concept study, ATSDR estimates that it will take 48 education specialists and 150 adult and 50 pediatric medical record specialists to complete record abstractions across all study sites. Given the goal to enroll at least 2,000 adults and 667 children per year, the annual time burden for medical and educational record abstraction is estimated to be 1,091 hours.

The total annualized time burden requested is 5,269 hours. There is no cost to the respondents other than their time.

**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)	
Multi-site Study Participants	Eligibility Screening Script	2,800	1	10/60	467	
	Appointment Reminder Telephone Script	2,667	1	5/60	222	
	Update Contact Information Hardcopy Form	2,667	1	5/60	222	
	Medication List	2,667	1	3/60	133	
	Body and Blood Pressure Measures Form	2,667	1	5/60	222	
	Blood Draw and Urine Collection Form	2,667	1	10/60	444	
	Adult Questionnaire	2,000	1	30/60	1,000	
	Child Questionnaire—Long Form	537	1	30/60	268	
	Child Questionnaire—Short Form	133	1	15/60	33	
	Parent Neurobehavioral Test Battery	667	1	15/60	167	
	Child Neurobehavioral Test Battery	667	1	90/60	1,000	
	Education Specialists	Child School Record Abstraction Form	48	14	20/60	224
		Medical Record Abstraction Form—Adult	150	13	20/60	650
Medical Record Specialists	Medical Record Abstraction Form—Child	50	13	20/60	217	
<b>Total</b>					<b>5,269</b>	

**Jeffrey M. Zirger,**

*Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.*

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**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60-Day--19-0457; Docket No. CDC-2019-0032]**

**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 Aggregate Reports for Tuberculosis Program Evaluation. The goal of the study is to allow CDC to collect and monitor indicators for key program activities, such as finding tuberculosis infections in recent contacts of cases

and in other high-risk persons likely to be infected and providing therapy for latent tuberculosis infection in an effort to eliminate Tuberculosis in the United States. CDC is requesting approval for 268 burden hours. This is an increase of 42 hour from the previously approved 226 hours.

**DATES:** CDC must receive written comments on or before June 24, 2019.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2019-0032 by any of the following methods:

- *Federal eRulemaking Portal:*

*Regulations.gov.* Follow the instructions for submitting comments.

- *Mail:* Jeffrey M. Zirger, Ph.D., 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. 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 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 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**

Aggregate Reports for Tuberculosis Program Evaluation (OMB No. 0920-0457, Expiration date 2/29/2020)—Revision—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

CDC requests approval of this revision of the Aggregate Reports for Tuberculosis Program Evaluation, previously approved under OMB No. 0920-0457, for three years. There are minor revisions to the report forms, data definitions, and reporting instructions.

CDC is requesting approval for 268 burden hours. This is an increase of 42 hours from the previously approved 226 hours. The minor revisions that contributed to an increase in data collection burden address the change in the national strategies for TB control and prevention, emphasizing treatment of individuals with latent TB infection (LTBI), and at high risk of progression to TB disease. The revisions, which are

optional data collection elements, will help programs assess high-risk populations served, and evaluate the adaptation and effectiveness of new diagnostic tests and drug regimens in treating LTBI.

To ensure the elimination of tuberculosis in the United States, CDC monitors indicators for key program activities, such as finding tuberculosis infections in recent contacts of cases and in other persons likely to be infected and providing therapy for latent tuberculosis infection. In 2000, CDC implemented two program evaluation reports for annual submission: Aggregate report of follow-up and treatment for contacts of tuberculosis cases, and Aggregate report of targeted testing and treatment for latent tuberculosis infection (OMB No. 0920-0457). The respondents for these reports are the 67 state and local tuberculosis control programs receiving federal cooperative agreement funding through the CDC Division of Tuberculosis Elimination (DTBE). These reports emphasize treatment outcomes, high-priority target populations vulnerable to tuberculosis, and electronic report entry and submission to CDC through the National Tuberculosis Indicators Project (NTIP), a secure web-based system for program evaluation data. No other federal agency collects this type of national tuberculosis data, and the aggregate report of follow-up and treatment for contacts of tuberculosis cases, and aggregate report of targeted testing and treatment for latent tuberculosis infection are the only data source about latent tuberculosis infection for monitoring national progress toward tuberculosis elimination with these activities. CDC provides ongoing assistance in the preparation and utilization of these reports at the local and state levels of public health jurisdiction. CDC also provides respondents with technical support for the NTIP software. The estimated annualized burden hours are 268. There is no cost to respondents other than their time.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Data clerks and Program Managers (electronic).	Follow-up and Treatment of Contacts to Tuberculosis Cases Form (3a).	67	1	2	134

## ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Data clerks and Program Managers (electronic).	Targeted Testing and Treatment for Latent Tuberculosis Infection (3b).	67	1	2	134
Total .....	.....	.....	.....	.....	268

**Jeffrey M. Zirger,**

*Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.*

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**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[30-Day-19-1170]

#### Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled *Canine Leptospirosis Surveillance in Puerto Rico* to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on January 29, 2019 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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 submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

#### Proposed Project

*Canine Leptospirosis Surveillance in Puerto Rico* (OMB Control No. 0920-1170, Exp. Date 03/31/2019)—Reinstatement with Change—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), National Center for Emerging and 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 to the approved ICR “*Canine Leptospirosis Surveillance in Puerto Rico*.” Approved methods of information collection will not change.

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 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. 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 being collected include information about the dog’s signalment, location of residence, environmental risk factors, vaccination history, clinical signs and symptoms,