

**CDC Burden of Canine  
Brucellosis Information Collection**

New Information Collection Request

**Supporting Statement – Section A**

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## Table of Contents

1. Circumstances Making the Collection of Information Necessary Background	3
2. Purpose and Use of the Information Collection	4
3. Use of Improved Information Technology and Burden Reduction	5
4. Efforts to Identify Duplication and Use of Similar Information	5
5. Impact on Small Businesses or Other Small Entities	5
6. Consequences of Collecting the Information Less Frequently	6
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5	6
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency	6
9. Explanation of Any Payment or Gift to Respondents	6
10. Assurance of Confidentiality Provided to Respondents	6
10.1 Privacy Impact Assessment Information	7
11. Justification for Sensitive Questions	7
12. Estimates of Annualized Burden Hours and Costs	7
13. Estimates of Other Total Annual Cost Burden to Respondents Or Record Keepers	8
14. Annualized Cost to the Government	8
15. Explanation for Program Changes or Adjustments	9
16. Plans for Tabulation and Publication and Project Time Schedule	10
17. Reason(s) Display of OMB Expiration Date is inappropriate	10
18. Exceptions to Certification for Paperwork Reduction Act Submissions	10
LIST OF ATTACHMENTS – Section A	10
References	11

1.

- The purpose of this information collection request is to estimate the burden of canine brucellosis in the United States.
- This will aid in the determination of the level of public health importance of human *B. canis* infections, and the potential for transmission of brucellosis from dogs, which will guide future human health research.
- Veterinary diagnostic laboratory directors will be solicited to participate in an online information collection to identify canine brucellosis diagnostic tests performed, and number of submissions per test, at their laboratory.
- Descriptive statistical analysis will be performed in Epi Info 7 and SAS 9.3.

This new Information Collection Request (ICR) titled “CDC Burden of Canine Brucellosis Information Collection” is requested for six (6) months to ensure unforeseen circumstances do not hinder data collection.

Zoonotic diseases comprise 61% of the infectious diseases affecting humans, and 75% of emerging diseases are zoonotic<sup>2</sup>. Brucellosis is a well-known zoonotic disease when transmitted from the host livestock animal to humans. The causative agents in livestock animals that are known to be pathogenic to humans are *Brucella abortus*, *suis*, and *melitensis*<sup>3</sup>. These species are considered smooth strains based on properties of the outer cell membrane. *Brucella canis*, which was first identified in canines in 1966, has a rough outer cell membrane<sup>4</sup>. It was also found to be pathogenic to humans, although it is considered less pathogenic than the aforementioned *Brucella* species.<sup>3,4</sup> Unlike *Brucella abortus*, *B. melitensis*, and *B. suis*, *B. canis* is not classified as a select agent, or an agent possessing the ability to pose a severe threat to public health and safety<sup>15</sup>.

Extensive efforts have been led by the United States Department of Agriculture to eradicate brucellosis in livestock due to the high economic cost of the disease and the impact on human health<sup>5</sup>. These efforts, however, are not targeted to *B. canis*, since it affects dogs which are companion animals, and economic impact has not been assessed.

Few seroprevalence studies have been done to estimate the prevalence of canine brucellosis; those that are published were conducted over 25 years ago<sup>6,7</sup>. Two recent reports from Oklahoma and Wisconsin describe increasing prevalence in dogs; however, the national burden is not known<sup>8,9</sup>. Dogs spread the infection through contact with infected body fluids. Semen and birth products contain the highest bacterial load, but organisms can be spread in blood, urine, and saliva<sup>10</sup>. Almost 60 *B. canis* human infections have been reported in the literature (CDC, unpublished data). Some human cases have reported assisting dogs with birthing<sup>11,12</sup>, but others have reported only casual contact with pet or stray dogs<sup>13,14</sup>.

Laboratory identification of the organism in humans does not require reporting to the Laboratory Response Network since it is not a select agent<sup>15,16</sup>. *Brucella* species-specific data are not collected in the Nationally Notifiable Disease Surveillance System at CDC, and there are no known, validated

*Brucella canis* serological tests to diagnose disease in humans<sup>17</sup>. For these reasons, there are no national estimates of *B. canis* prevalence in humans. Therefore, human infections are likely underdiagnosed and underreported<sup>10</sup>.

Neither the prevalence of canine brucellosis caused by species other than *B. canis* (such as *B. suis*, *B. abortus*, and *B. melitensis*) nor the potential risk of spread to humans is known. Canine infections with *Brucella* species (other than *B. canis*) have been reported in the literature<sup>18</sup>, and at least one human infection with *B. suis* related to canine contact has been reported<sup>19</sup>. Zoonotic transmission is a concern, and should be evaluated.

Recently, there has been interest in human brucellosis caused by *B. canis* among the public health community, due to recent reporting of human cases to CDC. The degree of public health importance of human *B. canis* infections has not yet been ascertained. The Council of State and Territorial Epidemiologists approved a position statement in 2012 that recommends increased focus on *B. canis*, and urges CDC to support the development of a human diagnostic assay<sup>17</sup>.

Additionally, states with higher prevalence can be targeted for future communication campaigns and focused activities to identify human cases, which can help to validate a human diagnostic assay. Veterinary diagnostic laboratories (**Attachment C-Veterinary Diagnostic Laboratories**) will be solicited to identify canine brucellosis diagnostic tests performed, and number of submissions per test at their laboratory. Data gathered through this Information Collection will be compiled to assist in estimating the burden of canine brucellosis in the United States.

Data will be collected from 119 U.S. state and territorial veterinary diagnostic laboratory directors acting in their official capacities. These diagnostic laboratories are located in 49 states and 1 territory.

This information collection is authorized by the Public Health Service Act (42 U.S.C. 241) (**Attachment A-Authorizing Regulations\_T42\_section\_241**).

## 2. Purpose and Use of the Information Collection

The purpose of this one-time information collection request conducted by CDC through a web survey of veterinary diagnostic laboratories is to estimate the burden of canine brucellosis in the United States. This information will provide an estimate of the potential transmission between dogs and humans, and determine the need for future human public health studies, which is critical during this time of scarce resources. Additionally, states with higher prevalence can be targeted for future communication campaigns, and focused activities to identify human cases which can help to validate a human diagnostic assay.

Overview of the Data Collection System – The data collection system consists of a web-based questionnaire (**Attachment D- Instrument\_Word Version, Attachment E- Instrument\_Web Version**) designed to assess the Laboratory Directors of State Veterinary Diagnostic Laboratories regarding the quantity of canine diagnostics requested, performed, and positive for brucellosis. The data collection instrument will be administered as a web-based instrument. The information collection instrument was reviewed by the Bacterial Special Pathogens Branch (BSPB) Zoonotic and Select Agent Laboratory, two representatives at a federal veterinary diagnostic laboratory, a veterinarian from a state public health department, and one representative at a state veterinary diagnostic laboratory. It was then pilot tested by 4 in-house CDC personnel. Feedback from these

groups was used to refine questions as needed, ensure accurate programming and skip patterns, and establish the estimated time required to complete the information collection instrument.

### **3. Use of Improved Information Technology and Burden Reduction**

All data collection will occur (100%) via a web-based questionnaire using Epi-Info 7, allowing respondents to complete and submit their responses electronically. This method was chosen to reduce the overall burden on respondents. The information collection instrument was designed to collect the minimum information necessary for the purposes of this project (i.e., limited to 22 questions).

The Information Collection will be emailed directly to the Laboratory Director or the main mailbox for each laboratory. Additionally, notices will be shared with members of AAVLD and the National Association of State Public Health Veterinarians.

The email will contain an introductory letter (**Attachment G-- Introductory Email**) requesting the participation of the laboratory, a link to the web-based information collection instrument hosted through Epi Info Web Survey, and a PDF version of the instrument. The PDF will allow the lab to look up the requested information at one time, and then enter the data. Epi Info Web Survey received an ATO on July 10, 2012 under a Low EMSSP used by the CDC's Office of the Chief Information Security Officer (OCISO). Everything is Low across the board and this system does not contain PII. The collected data will be stored on internal (ITSO) CDC servers that are fully CDC compliant. The data will be received electronically and stored in an Epi-Info database. These data are only shared with BSPB, and only those BSPB staff who work directly on the project will have access to the folder.

### **4. Efforts to Identify Duplication and Use of Similar Information**

Individuals at the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS), as well as the Wisconsin State Public Health Veterinarian (who has recently done an exhaustive white paper on *Brucella canis*) were queried. According to these sources, this information has never been systematically collected from the State Veterinary Diagnostic Laboratories. This information does not exist in any formal document.

### **5. Impact on Small Businesses or Other Small Entities**

A few small businesses will be involved in this data collection, as there are very few small veterinary diagnostic laboratories remaining in the United States. We hypothesize that these labs outsource most if not all *Brucella* testing to larger laboratories, due to the unavailability of some rapid diagnostic tests, and regulations surrounding *Brucella* isolation.

### **6. Consequences of Collecting the Information Less Frequently**

This is a one-time data collection. There are no legal obstacles to reduce the burden. Without these data:

- There would be no estimate of burden of canine brucellosis in the United States
- CDC would lack evidence to support the development of studies for human *B. canis* infections and development of diagnostic assays

- CDC would not be able to provide responses on disease prevalence when requests are received

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

This request fully complies with the regulation 5 CFR 1320.5.

## 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

- A. A 60 day notice was published in the Federal Register on 05/19/2015, vol. 80, p. 28617 (**Attachment B- 60 Day Federal Register Notice**). No public comments were received.
- B. We contacted Sarah Tomlinson (National Animal Health Laboratory Network Coordinator, [Sarah.m.tomlinson@aphis.usda.gov](mailto:Sarah.m.tomlinson@aphis.usda.gov)) and Matthew Erdman (Diagnostic Bacteriology Laboratory Director, [matthew.m.erdman@aphis.usda.gov](mailto:matthew.m.erdman@aphis.usda.gov)) with the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) and James Kazmierczak (State Public Health Veterinarian, [james.kazmierczak@wi.gov](mailto:james.kazmierczak@wi.gov)) with the Wisconsin Department of Health Services. According to these sources, this information has never been systematically collected from the State Veterinary Diagnostic Laboratories. This information does not exist in any formal document.

## 9. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

## 10. Assurance of Confidentiality Provided to Respondents

The Privacy Act does not apply to this data collection. Laboratory employees will not be asked, nor will they provide individually identifiable information. This data collection is not research involving human subjects.

### Items of Information to be Collected –

There are a total of 22 questions on the Information Collection, 11 of which have at least one subpart. There are 134 check-box questions which ask about the type of facility, data storage, number of specimens received per canine, outsourcing of clinical testing, state-wide policies for reporting of positive results, policies for human exposure to isolates, and requesting interest in future CDC studies; one question has a drop down pick list. There is one table which requests the tests used to diagnose *Brucella canis* in dogs over the past 5 years. There are ~~four~~three open-ended/free-text questions requesting laboratory name, and more details on laboratory tests and policies; one question asks for estimated counts by reason of sample submission. The multipart questions ask about the amount of testing done in-house versus outsourced, the number of specimen types submitted, the number of samples that were positive, and the number of dogs that this represents (multiple samples might be sent per animal). A question has been included to assess the completeness of each laboratory's data over the 5 year period. For those questions that request data for a given time period, the instrument will modify the time period based on the response to this completeness question. This could affect analysis of trends, but infections can be estimated on an annual basis.

All questions are designed to receive information on the quantity of tests and procedures diagnosing canine brucellosis, the understanding of state policies, and internal policies and exposure histories at state veterinary diagnostic laboratories. More specifically:

- Quantity of tests and diagnostic procedures is addressed in Questions 7-15 of “Burden of Canine Brucellosis Information Collection Instrument.”
- Understanding of state policies, internal policies, and exposure histories is addressed in Questions 16-22 of “Burden of Canine Brucellosis Information Collection Instrument.”

IRB Determination is attached (**Attachment K**)

### **10.1 Privacy Impact Assessment Information**

No individually identifiable information (IIF) will be collected.

### **11. Justification for Sensitive Questions**

No information will be collected that is of personal or sensitive nature.

### **12. Estimates of Annualized Burden Hours and Costs**

The estimate for burden hours is based on a pilot test of the information collection instrument by four public health professionals. Fewer than nine people participated in the pilot. In the pilot test, the average time to complete the information collection including time for reviewing instructions, gathering needed information and completing the information collection instrument, was approximately 37.5 minutes. Based on these results, the estimated time range for actual respondents to complete the instrument is 30-60 minutes, factoring in time for some Laboratory Directors to consult with other employees and querying their database before completing the information collection instrument. For the purposes of estimating burden hours, the upper limit of this range (i.e., 60 minutes) is used.

Since we do not have experience with this group, it is difficult to estimate non-responder rate. To estimate burden time for administering this telephone reminder to the known laboratories (n=119), we have over-estimated the non-responders to be 100% to ensure there is sufficient burden time, although we do not believe the non-response will be this high. All non-responders will be phoned. The telephone reminder will take no more than five (5) minutes per call, which is used to estimate burden.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for management occupations – medical and health services managers in state government (<http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf>). Based on DOL data, an average hourly wage of \$42 is estimated for all 129 respondents. Table A-12 shows estimated burden and cost information.

**Table A-12.A:** Estimated Annualized Burden Hours and Costs to Respondents –Information Collection

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Veterinary diagnostic laboratory staff	Burden of Canine Brucellosis Information Collection Instrument	119	1	1	119
Non-responders (over-estimation)	Telephone Script	119	1	5/60	10
Other laboratories	Burden of Canine Brucellosis Information Collection Instrument	10	1	1	10
<b>TOTALS</b>		<b>129</b>			<b>139</b>

**Table A-12.B:** Estimated Annualized Costs to Respondents –Information Collection

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Veterinary diagnostic laboratory staff	Burden of Canine Brucellosis Information Collection Instrument	119	42.00	\$4998.00
Veterinary diagnostic laboratory staff	Telephone Script	10	42.00	\$420
Other laboratories	Burden of Canine Brucellosis Information Collection Instrument	10	42.00	\$420
<b>TOTALS</b>		<b>139</b>	<b>42.00</b>	<b>\$5,838.00</b>

### 13. Estimates of Other Total Annual Cost Burden to Respondents Or Record Keepers

There will be no direct costs to the respondents other than their time to participate in the information collection.

### 14. Annualized Cost to the Government

There are no equipment or overhead costs. The cost to the federal government will be the cost of a student as well as the salary of the CDC staff supporting the information collection activities and associated tasks. The student will develop the electronic information collection tool. The CDC staff



has developed the information collection materials, will send the collection tool, remind respondents to complete the information collection instrument, receive the data, conduct analyses, and generate the report.

The estimated average annual cost to the federal government for the proposed information collection activities is \$4981.50. This figure encompasses 80 hours FTE of one GS-12 employee, 25 hours FTE of one commissioned corps employee, and 20 hours for one student. The average hourly rate was obtained from the Office of Personnel Management’s website (<http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2013/general-schedule/atlanta-sandy-springs-gainesville-ga-al-hourlyovertime-rates-by-grade-and-step/>). The hourly rate for a GS-12 in metro Atlanta is \$34.80 per hour, which is about \$72,620 per year. The hourly rate for a commissioned corps veterinary epidemiologist in metro Atlanta is \$48.00 per hour, which is about \$100,165 per year.

Table A-14 describes how this cost estimate was calculated.

**Table A-14:** Estimated Annualized Cost to the Federal Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Brucellosis Epidemiologist (GS-12) Develop data collection tool and project materials, identify respondents, follow up with non-responders, conduct analyses, generate report	80	\$34.80	2784.00
Brucellosis Veterinary Epidemiologist (Commissioned Corps) Review and advise on material development, advise and assist with analysis and report writing.	25	\$48.00	1200.00
Information Collection Developer (Student) Develop the electronic data collection tool, send Information Collection request, receive the data, and share the data with the CDC project staff	20	\$6.00	120.00
<b>Estimated Total Cost of Information Collection</b>			<b>\$4,104</b>

**15. Explanation for Program Changes or Adjustments**

This is a new data collection.

**16. Plans for Tabulation and Publication and Project Time Schedule**

The data will be collated and analyzed by the Brucellosis Epidemiologist and Brucellosis Veterinary Epidemiologist. The results will be compiled into a manuscript for publication in the scientific literature, which will be cleared by the Bacterial Special Pathogens Branch and Division of High-Consequence of Pathogens and Pathology leadership.

Project Time Schedule

Action	Timeline
Information Collection to be sent	2 weeks following OMB approval
Data collection	1 month to complete
1 <sup>st</sup> e-mail reminder sent	1 week after date due
2 <sup>nd</sup> e-mail reminder sent	2 weeks after date due
Telephone reminder	3 weeks after date due
Final collection of data	2 months after Information Collection sent
Data validation	2 weeks
Data analysis	1 month
Report generated and shared	3 months

**17. Reason(s) Display of OMB Expiration Date is inappropriate**

We are requesting no exemption.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

**LIST OF ATTACHMENTS – Section A**

Note: Attachments are included as separate files as instructed.

- A- Authorizing Regulations T42 section 24**
- B- 60 day Federal Register Notice**
- C- Veterinary Diagnostic Laboratories**
- D- Instrument Word Version**
- E- Instrument Web Version**
- F- Vet Labs List**
- G- Introductory Email**
- H- Notice**
- I- Reminder Email**
- J- Telephone Script**
- K- IRB determination**

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