U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Print Date: 9/25/23

Title: Chronic Q Fever in the United States Advanced Clinical Surveillance Amendment 1

Project Id: 0900f3eb82219553

Accession #: NCEZID-EPI-12/6/18-c6a94

Project Contact: David McCormick

Organization:

Status: **Pending Clearance : Amendment**

Intended Use: **Project Determination**

Estimated Start Date: 12/31/2018

Estimated Completion Date: 12/31/2029

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #: seeking to add a module to existing surveillance under OMB 0920-0009

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research - Public Health Surveillance *45 CFR 46.102(l)(2)*	9/25/23	Youngblood_Laura L. (zfk9) CIO HSC
PRA: **PRA Applies**		9/25/23	Vice_Rudith (nhr9) OMB / PRA

ICRO: **Returned with No Decision**		9/30/20	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority:	Urgent
Date Needed:	09/26/2023
Priority Justification:	Determination from HRSO needed by 9/26 to ensure compliance with OMB/PRA deadlines.
Determination Start Date:	09/18/23
Description:	Currently, chronic Q fever cases are reported via the National Notifiable Disease Surveillance System, and supplementary clinical, laboratory, and demographic data are collected using a case report form (CRF). Acute and chronic Q fever cases are still reported using the same CRF, with risk factor, exposure history, and clinical questions applied to both forms of the disease. This limits the amount and quality of data collected about chronic Q fever in particular, since its presentation is very different from acute Q fever. Only endocarditis and hepatitis are listed as options for clinical disease on the current CRF; data on osteomyelitis, osteoarthritis, or vascular infections are not systematically collected. It is unknown how frequently, or in what patients, these other chronic Q fever presentations occur in the United States. We are creating an enhanced surveillance module for chronic Q fever to answer these unknowns. Additionally, data regarding case progression for patients with Q fever are limited. We plan to collect data from the treating physician regarding clinical course, treatment, and complications over a two-year period for each patient in order to improve the efficacy and accuracy of clinical consultations provided by CDC.
IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission:	No
IMS Activation Name:	Not selected
Primary Priority of the Project:	Not selected
Secondary Priority(s) of the Project:	Not selected
Task Force Associated with the Response:	Not selected
CIO Emergency Response Name:	Not selected
Epi-Aid Name:	Not selected
Lab-Aid Name:	Not selected
Assessment of Chemical Exposure Name:	Not selected
Goals/Purpose	The goal of the project is to gather additional and more specific clinical data not otherwise collected during the course of routine surveillance for chronic Q fever. This information will allow for better characterization of the clinical presentation and risk factors of chronic Q fever in the United States. Systematically collect detailed information on the disease manifestations, clinical management, and epidemiology of chronic Q

Objective:	fever.
Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?:	No
Does your project investigate underlying contributors to health inequities among populations /groups experiencing social, economic, geographic, and/or environmental disadvantages?:	No
Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?:	No
Activities or Tasks:	New Collection of Information, Data, or Biospecimens
Target Populations to be Included/Represented:	General US Population
Tags/Keywords:	Coxiella burnetii ; Q Fever ; Public Health Surveillance
CDC's Role:	Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided
Method Categories:	Surveillance Support
Methods:	The purpose of this project is to obtain additional clinical and epidemiological information on cases of chronic Q fever for which RZB staff is consulted by the provider. After assisting the clinician with his/her clinical management questions, an RZB staff member will complete a REDCap survey by asking questions of the requesting clinician (Attachment 3). The Chronic Q Fever Case Investigation Form collects different data than the standard surveillance case report form and will not duplicate data collection efforts already in place. The name and contact information for the requesting clinician, but not the patient, will be collected in order to facilitate follow-up. At intervals of 6, 12, 18, and 24 months after the initial consult, an RZB staff member will recontact the requesting clinician and administer the follow-up questionnaire (Attachment 4). Chronic Q fever cases are defined as those patients who meet the clinical and laboratory criteria defined by the Council for State and Territorial Epidemiologists (CSTE) for a chronic Q fever case (Appendix 4). Typically, Phase I IgG exceeds Phase II IgG in chronic disease; however those with appropriate clinical disease manifestations (endocarditis, vascular infection, osteomyelitis/osteoarthritis, chronic hepatitis) that have a reciprocal IgG antibody titer of Phase I >800 will be included, regardless of Phase II levels.
Collection of Info, Data or Biospecimen:	# RZB staff members will enter data into a CDC REDCap database. # Data collection topics will include basic demographics, previous Q fever history, patient risk factors, clinical findings, laboratory and other diagnostic data, treatment information, and case outcome. # Personally identifiable information on the patient will not be collected or included in the electronic data used for analysis. # This is a growing dataset with open enrollment; whenever RZB staff identify an appropriate case, we will invite the clinician to participate in the enhanced surveillance component.
Expected Use of Findings/Results and their impact:	# The results from this project will be summarized regularly. The results will be included in a manuscript and submitted for publication in the peer-reviewed literature when of public health interest. # The results of this analysis are intended for physicians and medical researchers studying chronic Q fever. The results will help characterize an under-recognized disease and help educate physicians on identifying, diagnosing, and treating these cases.
Could Individuals potentially be identified based on Information Collected?	No

Funding

Funding yet to be added .....

HSC Review

Regulation and Policy

Do you anticipate this project will need IRB review by the CDC IRB, NIOSH IRB, or through reliance on an external IRB?

Estimated number of study participants

Population - Children	Protocol Page #:
Population - Minors	Protocol Page #:
Population - Prisoners	Protocol Page #:
Population - Pregnant Women	Protocol Page #:
Population - Emancipated Minors	Protocol Page #:

Suggested level of risk to subjects

Do you anticipate this project will be exempt research or non-exempt research

Requested consent process waviers

Informed consent for adults	No Selection
Children capable of providing assent	No Selection

Parental permission	No Selection
Alteration of authorization under HIPPA Privacy Rule	No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection

Consent process shown in an understandable language

Reading level has been estimated	No Selection
Comprehension tool is provided	No Selection
Short form is provided	No Selection
Translation planned or performed	No Selection
Certified translation / translator	No Selection
Translation and back-translation to/from target language(s)	No Selection
Other method	No Selection

Clinical Trial

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection
Evaluation of a health related biomedical or behavioral outcome	No Selection
Registerable clinical trial	No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus	No Selection
Human genetic testing is planned now or in the future	No Selection

Involves long-term storage of identfiable biological specimens	No Selection
Involves a drug, biologic, or device	No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	No Selection

Institutions & Staff

Institutions

Institutions yet to be added .....

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
David McCormick	04/17/2026	07/05/2026	07/05/2026	07/05/2026	Principal Investigator	yup1@cdc.gov	970-225-4272	EPIDEMIOLOGY
Nicolette Bestul	08/07/2026				Co-Investigator	pue8@cdc.gov	404-718-3827	EPIDEMIOLOGY
Paige Armstrong	02/28/2025	09/29/2024		09/29/2024	Co-Investigator	yzu9@cdc.gov	404-639-8450	EPIDEMIOLOGY

Data

DMP

Proposed Data Collection Start Date:	2/1/19
Proposed Data Collection End Date:	12/31/28
Proposed Public Access Level:	Restricted

Restricted Details:

Data Use Type: Data Sharing Agreement

Data Use Type URL:

Data Use Contact:

Public Access Justification:

How Access Will Be Provided for Data:

Plans for Archival and Long Term Preservation:

Spatiality

Country	State/Province	County/Region
United States		

Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									

Supporting Info

No Supporting Info

U.S. Department of Health and Human Services

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