

CryptoNet Case Report Form
Request for OMB approval of a New Information Collection Instrument

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Supporting Statement A

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- **Goal of the study:** The goal of the CryptoNet Case Report Form (CRF) is to define a set of data elements that can be used to identify exposure trends in outbreak- and non-outbreak-associated *Cryptosporidium* cases, to generate hypotheses about the source(s) of infection in clusters or outbreaks, and to identify strategies to prevent and control cases, clusters, or outbreaks.
- **Intended use of the resulting data:** The CRF will be used by federal, state, and local public health officials responsible for conducting interviews with reported cases of cryptosporidiosis in their jurisdiction in order to systematically assess core exposure elements and risk factors among cases of cryptosporidiosis. Collected data will be used by CDC staff to inform cryptosporidiosis sporadic case and cluster and outbreak prevention and control strategies.
- **Methods to be used to collect:** The CRF data elements and form were designed for administration via telephone interviews.
- **Respondent population:** Individuals ill with cryptosporidiosis, or their designated proxy.
- **How data will be analyzed:** Primarily univariate analyses of exposures, risk factors, and demographic characteristics among cryptosporidiosis case patients interviewed. Statistical software like SAS and R will be used for analyses.

1. Circumstances Making the Collection of Information Necessary

This is a new Information Collection Request. We are requesting approval for a period of 36 months.

The Waterborne Disease Prevention Branch (WDPB) in the Division of Foodborne, Waterborne, and Environmental Diseases (DFWED) works to prevent domestic and global water, sanitation, and hygiene (WASH) related disease. WDPB is comprised of four teams, including the Domestic WASH Epidemiology Team, which focuses on the prevention and control of waterborne and WASH-related disease and outbreaks in the United States. One of the diseases included in the team's work is cryptosporidiosis, an acute diarrheal disease caused by infection with *Cryptosporidium* parasites.

The Case Surveillance node is a sub-unit within the Domestic WASH Epidemiology Team which focuses on the data collection and management activities of six waterborne diseases, including cryptosporidiosis, in the United States. The Case Surveillance node's current scope of work includes modernizing data collection and management, enabling data connections, and improving public data access to aid public health action. The Case Surveillance node has primary oversight of the CryptoNet epidemiology activities. CryptoNet is the first molecular tracking system for *Cryptosporidium* in the United States. The Case Surveillance node also collaborates with other groups in WDPB and DFWED that engage in *Cryptosporidium* related activities. This includes, but is not limited to, the CryptoNet laboratory; DFWED Surveillance, Information Management, and Statistics Office; and Outbreak Response and Prevention Branch.

Cryptosporidium are a genus of parasites that cause the diarrheal disease cryptosporidiosis [1]. It is estimated that *Cryptosporidium* causes around 800,000 cases of diarrhea in the United States annually [2, 3]. *Cryptosporidium* parasites are spread through the fecal-oral route [4]. This can occur when hands can become contaminated with the feces of someone sick with cryptosporidiosis, contaminated food or water are ingested [2, 3], contact with infected animals, their feces, or their environment [5], or if contaminated objects come into contact with one's mouth. *Cryptosporidium* parasites have also been reported to survive on a range of surfaces and have shown resistance to many otherwise effective

disinfectants [1]. Strategies to prevent becoming sick with cryptosporidiosis include washing hands, following safe food and water behaviors at home and when travelling, avoiding swallowing water when swimming, and washing hands with soap and water following animal contact or contact with their environment. To prevent secondary transmission of cryptosporidiosis among individuals who are sick, prevention behaviors include washing hands, avoiding cooking for others when sick, and avoiding swimming until fully recovered.

From 2009 through 2017, there were 444 outbreaks of cryptosporidiosis in the United States, with most of these outbreaks attributed to treated recreational water (156, 35%) [4]. Outbreaks of cryptosporidiosis have been reported in a range of settings such as treated [6-14] and untreated recreational water venues [9, 15], daycares [16-19], farms and petting zoos [5]. Outbreaks of cryptosporidiosis have impacted a range of populations such as children, individuals with HIV [20], men who have sex with men [21], and veterinary students and others who work closely with animals [22-29]. Finally, outbreaks of cryptosporidiosis have been attributed to a range of transmission modes including person-to-person/no common source [16-19, 30], animal contact [5, 22-29, 31, 32], contaminated food [33-44], and contaminated water [6-15, 45].

As part of *Cryptosporidium* case and outbreak investigations, it is common for state and local health departments to conduct comprehensive interviews with cases and contacts to identify how individuals became sick with cryptosporidiosis, to identify individuals who could have come into contact with an individual sick with cryptosporidiosis, and to identify strategies to control the disease spread. Since cryptosporidiosis can be transmitted through numerous modes, it can be challenging to identify how individuals could have become ill. As a result, comprehensive case report forms focused on a range of settings, activities, and potential modes of transmission are needed to guide prevention and control activities.

CryptoNet and the Case Surveillance node, in collaboration with other branches in DFWED, are responsible for supporting investigations of cryptosporidiosis, and for providing technical assistance for clusters and outbreaks upon request by local jurisdictions. Cryptosporidiosis cases, clusters, and outbreaks are identified through CryptoNet laboratory molecular subtyping, states reaching out to CDC for technical assistance, through healthcare professionals contacting CDC, state, or local health departments, and through media scans. To improve the ability of CryptoNet and the Case Surveillance node to investigate, respond, and prevent and control clusters and outbreaks of cryptosporidiosis, there is a need for CryptoNet, the Case Surveillance node, and state and local jurisdictions to be able to collect case interview data in a systematic way when laboratory confirmed *Cryptosporidium* cases, clusters, and outbreaks are identified.

The primary audiences for this project are (1) state and local public health partners (enteric disease epidemiologists, public health nurses, and other interviewers) and (2) the CDC. The maintenance of the data collection instrument and the associated data will be coordinated by the CryptoNet and the Case Surveillance node in the Waterborne Disease Prevention Branch in the Division of Foodborne, Waterborne, and Environmental Diseases at CDC.

Authorizing Legislation comes from Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment A).

2. Purpose and Use of Information Collection

To meet the needs of the CryptoNet, the Case Surveillance node, and the needs of local officials, CryptoNet case report form (CRF) was developed. The CRF includes a set of data elements that can be

used to identify exposure trends in outbreak- and non-outbreak-associated *Cryptosporidium* cases, to generate hypotheses about the source(s) of infection in clusters or outbreaks, and to identify strategies to prevent and control *Cryptosporidium* cases, clusters, or outbreaks. CryptoNet is meant to supplement existing cryptosporidiosis case surveillance data reported through the National Notifiable Diseases Surveillance System (NNDSS, OMB No. 0920-0728, exp. 3/31/2024). Current cryptosporidiosis case surveillance through NNDSS lacks information on key exposures proposed to be captured by CryptoNet. Notably, information proposed to be collected as part of CryptoNet serves as the foundation for the recently developed foodborne and diarrheal diseases message mapping guide - cryptosporidiosis tab (FDD MMG). The FDD MMG is the latest revision to NNDSS that aims to increase the amount of exposure data collected on each cryptosporidiosis case; however, full implementation of the FDD MMG must be phased in over a period of years. At this time, NCEZID is requesting OMB approval of the CryptoNet Case Report Form to serve an immediate need to strengthen cryptosporidiosis case surveillance and public health response. Upon nationwide implementation of the FDD MMG, NCEZID anticipates that the CryptoNet Case Report form will be retired.

Administration of the CRF is to conduct surveillance on exposures associated with *Cryptosporidium* cases identified through CryptoNet laboratory molecular subtyping, states reaching out to CDC for technical assistance, through healthcare professionals contacting CDC, state, or local health departments, and through media scans to better inform prevention and control strategies for these infections. There are no research questions addressed. Standardized data will be compiled on recent exposures related to cryptosporidiosis with the intention to inform disease prevention and control activities and will not be used to inform generalizable knowledge. Staff in CryptoNet and the Case Surveillance node in WDPB will oversee data collection, data management, and analyses and dissemination of data collected with the CRF during cryptosporidiosis investigations. The data collected from the CRF will be used to inform exposure trends among cases, clusters, or outbreaks with the intention to identify and implement prevention and control strategies and recommendations.

3. Use of Improved Information Technology and Burden Reduction

The CRF data elements and form were designed for administration via telephone interview with cases of cryptosporidiosis or their proxies. This method was chosen to reduce the overall burden on respondents because it allows for the assessment team to ask for clarification from participants during the interview, and this limits the need for additional follow-up. The data collection instrument was designed to collect the minimum information necessary for the purposes of this project.

4. Efforts to Identify Duplication and Use of Similar Information

There is currently no data collection instrument in use to identify exposure trends in outbreak- and non-outbreak-associated *Cryptosporidium* cases, to generate hypotheses about the source(s) of infection in clusters or outbreaks, and to identify strategies to prevent and control *Cryptosporidium* cases, clusters, or outbreaks. Moreover, CryptoNet is meant to supplement existing cryptosporidiosis case surveillance data reported through NNDSS. Current cryptosporidiosis case surveillance through NNDSS lacks information on key exposures proposed to be captured by CryptoNet. Notably, information proposed to be collected as part of CryptoNet serves as the foundation for the recently developed FDD MMG - cryptosporidiosis tab. This information that will be gathered through the CRF is not currently available from other data sources or through other means. Prior to developing the CRF and this data collection activity, WDPB staff in CryptoNet and the Case Surveillance node consulted with internal stakeholders, including the NNDSS, to confirm that this effort is not duplicative.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection

6. Consequences of Collecting the Information Less Frequently

Lack of comprehensive data about cases of cryptosporidiosis will slow down the cluster and outbreak investigation process leading to potentially adverse health outcomes.

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

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). No special circumstances apply.

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

A 60-day Federal Register Notice was published in the *Federal Register* on March 8, 2021, vol. 86, No. 43, p. 13393-13394 (Attachment B). No public comments were received. No consultations outside of CDC occurred including with local health department partners.

9. Explanation of Any Payment or Gift to Respondents

There will be no remuneration to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The Privacy Act does not apply to this data collection (Privacy Impact Assessment, Attachment E). Only limited individually identifiable information - age, sex, race, ethnicity, and county of residence - is being collected.

Individuals and organizations will be assured of the privacy of their replies under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c). They will be told the purposes for which the information is collected and that, in accordance with this statute, any identifiable information about them will not be used or disclosed for any other purpose without their prior consent, unless required by law upon the demand of a court or other governmental authority.

CRF data will be securely shared with CDC by local officials, and data shared with CDC will be stored in a limited access folder and in a secure Access database housed behind the CDC firewall. Following data entry, the original paper version of the CRF form will be destroyed. Before data entry, the original paper version of the CRF will be kept in a locked file cabinet or in a folder on the limited access CDC drive.

The CRF data elements and CRF data collection tool will ascertain information from respondents about exposures (e.g., animal, food, water, person-to-person contact, travel) preceding onset of cryptosporidiosis, basic demographic information (e.g., age, sex, race, ethnicity, and residence state and county), associated laboratory testing information (e.g., test result and type of test conducted), and limited characteristics of case patient illness (e.g., illness onset and survival status). It will collect a limited set of information that could be used to identify individual case patients. Local or State public health officials with jurisdictional responsibility will maintain the respondent's name, telephone number, and personally identifiable information except age, sex, race, ethnicity, and county of residence. Personally identifiable information, except age, sex, race, ethnicity, and county of residence, will be not be included in the data collection tool and no other identifying information will be transmitted to CDC.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Institutional Review Board (IRB)

It has been determined that IRB review is not required for this data collection (Attachment D).

Justification for Sensitive Questions

Cryptosporidium parasites can be spread in multiple ways. This includes through contaminated food and water, contact with infected animals, and via sexual and non-sexual person-to-person contact. To determine if cases became ill via sexual person-to-person contact, case patients will be asked questions about recent sexual activity and the gender of sexual partners. This module is asked at the end of the CRF and case patients are provided the option to opt out of answering these questions or any other questions.

All questions in the CRF are optional, and case patients can choose to answer the questions they feel comfortable responding to.

12. Estimates of Annualized Burden Hours and Costs

- A. Interviews will be conducted with case patients ill with cryptosporidiosis or their proxies. Based on the number of cryptosporidiosis specimens submitted to the CryptoNet laboratory each year for testing, it is estimated that the CRF would be administered to approximately 500 individual respondents across all CryptoNet jurisdictions each year. The estimate for burden hours is based on a pilot test of the data collection instrument by 2 public health professionals. In the pilot test, the average time to complete the instrument including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 15 minutes (range: 10 to 20 minutes). For the purposes of estimating burden hours, the average time to complete the instrument was used. This new data collection will use qualitative methods, including telephone interviews guided by semi-structured protocols designed to elicit core elements exposures from respondents. There are no specific research questions addressed.

Exhibit 1: Estimated Annual Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Individuals ill with cryptosporidiosis, or their designated proxy.	CryptoNet Case Report Form	500	1	15/60	125 hours
Total					125 hours

Exhibit 2 shows the estimated annual cost burden associated with individual's time to participate. We used the 2019 mean average hourly wage for all occupations in the United States. This wage of \$25.72 was obtained from the Bureau of Labor Statistics (https://www.bls.gov/oes/current/oes_nat.htm#00-0000). Burden in hours is taken from Exhibit 1. The total annual cost burden is calculated by multiplying the mean hourly wage by the burden in hours. The total cost burden is estimated to be \$3,215.00.

Exhibit 2. Estimated Annual Burden Costs

Type of	Form Name	Total Burden	Hourly Wage	Total Respondent
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Respondent		Hours	Rate	Costs
All occupations in the United States	CryptoNet Case Report Form	125 hours	\$25.72	\$3,215.00
Total				\$3,215.00

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

There are no direct costs to respondents other than their time to participate in this study.

14. Annualized Cost to the Government

The estimated total cost to the Federal Government for this project is \$9,306 over a one-year period of data collection. Therefore, a three-year collection period is estimated to cost, \$27,918. Exhibit 3 provides a breakdown of the estimated total annual costs.

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Total Average Cost
Epidemiologist – (GS-12); Project development and project management, data analysis, publication, and dissemination of results	100	\$39.12	\$3,912.00
Epidemiologist (GS-9, equivalent) Data management, CryptoNet jurisdiction coordination, and data analysis	200	\$26.97	\$5,394.00
Estimated Total Cost of Information Collection			\$9,306.00

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Project Time Schedule	
Activity	Time Schedule
Utilize the CRF to conduct interviews during cryptosporidiosis case, cluster, and outbreak investigations	Months 1-36
Ongoing data analysis	Months 1-36

The analysis plan for data collected using the CRF is to conduct primarily univariate analyses of exposures, risk factors, and demographic characteristics among case patients interviewed as part of case, cluster, and outbreak investigations of cryptosporidiosis. Statistical software like SAS and R will be used for analyses. All data collected and databases will be housed on a secure drive on the CDC network that is only accessible to the project members.

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

None.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

- A. Section 301 of the PHS Act (42 U.S.C. 241)
- B. 60-Day Federal Register Notice
- C. CryptoNet Case Report Form (CRF)
- D. Determination of Non-Applicability of Human Subjects Regulations
- E. Privacy Impact Assessment (PIA)

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