

CryptoNet Case Report Form  
Request for Revision of a Currently Approved Collection  
(OMB No. 0920-1360)

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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. Data are analyzed within the secure, cloud-based data collection system and by analysts using statistical software like SAS and R.

### 1. Circumstances Making the Collection of Information Necessary

This is a revision Information Collection Request for the CryptoNet Case Report Form (OMB Control No. 0920-1360, expiration date 1/31/2025). We are requesting extended approval for a period of 36 months.

The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), 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 five teams, including the Domestic Waterborne Disease Epidemiology and Response (WDER) Team, which focuses on the prevention and control of waterborne 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 Program is a sub-unit within the Domestic WDER Team which focuses on the data collection and management activities of five waterborne diseases, including cryptosporidiosis, in the United States. The Case Surveillance Program'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 Program has primary oversight of the CryptoNet epidemiology activities. CryptoNet is the first molecular tracking system for *Cryptosporidium* in the United States. The Case Surveillance Program 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 (SIMSO); WDPB's Environmental Microbiology and Engineering Laboratory (EMEL); and DFWED's Outbreak Response and Prevention Branch (ORPB).

*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,

including 322,000 cases in 2014 due to recreational and drinking water exposures and non-recreation/non-drinking water exposures (e.g., water used for purposes other than drinking or recreation such as agriculture, industry, medical procedures) and can come from backcountry streams or flood waters [2, 3, 4]. *Cryptosporidium* parasites are spread through the fecal-oral route [6]. 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 [7], 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 traveling, 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 2022, there were 627 outbreaks of cryptosporidiosis in the United States causing at least 10,042 illnesses, 349 hospitalizations, and 2 deaths, with most of these outbreaks attributed to treated recreational water (205, 33%) [5]. Outbreaks of cryptosporidiosis have been reported in a range of settings such as treated [8-16] and untreated recreational water venues [11, 17], daycares [18-21], farms and petting zoos [7]. Outbreaks of cryptosporidiosis have impacted a range of populations such as children, individuals with HIV [22], men who have sex with men [23], and veterinary students and others who work closely with animals [24-31]. Finally, outbreaks of cryptosporidiosis have been attributed to a range of transmission modes including person-to-person/no common source [18-21, 32], animal contact [7, 24-31, 33, 34], contaminated food [35-46], and contaminated water [8-17, 47].

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 Program, 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. Since the initial CryptoNet CRF OMB approval in January 2021 until data were reviewed on October 4, 2024, data from 1,280 CRFs were entered into CDC's secure, cloud-based electronic surveillance system (i.e., System for Enteric Disease Response, Investigation, and Coordination [SEDRIC]). Respondents indicated that 90% cases were sporadic and not associated with an outbreak, 7% cases were associated with an outbreak, and for 3% of cases there was no information about its association with an outbreak. Most exposures were reported to have been drinking water (92%) contact with an animal (74%), and swimming (43%) (exposures not mutually exclusion). Data from the CRF enabled public health officials to identify outbreaks and exposures and target control measures.

To continue the CryptoNet and the Case Surveillance Program's ability to investigate, respond, and prevent and control cases, clusters and outbreaks of cryptosporidiosis, there is a need for CryptoNet, the Case Surveillance Program, and state and local jurisdictions to continue collecting 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 Program 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 Program, and the needs of local officials, CryptoNet case report form (CRF) was developed and received initial OMB approval in 2021. 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 Control No. 0920-0728, exp. 3/31/2027). Current cryptosporidiosis case surveillance through NNDSS lacks information on key exposures proposed to be captured by CryptoNet. Notably, information 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 Program 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**

The CryptoNet CRF is the only uniform, national 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. Information gathered through the CryptoNet CRF is not currently available from other data sources or through other means.

### **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). CDC is unable to implement the SPD-15 requirement for detailed race and ethnicity data into the CryptoNet case report form. The form and accompanying structure within SEDRIC was developed prior to SPD-15 release date. The race/ethnicity question and options do not follow the current guidance on SPD-15 because those options do not currently exist within the SEDRIC platform. If the race/ethnicity question and options need to be update per SPD-15, we would need to confirm the level of resources necessary to edit within SEDRIC platform. CDC is aiming to comply with the updated standards set for Federal data on Race and Ethnicity by and/or before the March 2029 deadline.

No other 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 October 21, 2024, vol. 89, No. 203, p. 84144 (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**

NCEZID's Information Systems Security Officer reviewed this submission and determined that there are no changes to the privacy aspects of this package. 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 and stored by CDC by local officials through the System for Enteric Disease Response, Investigation, and Coordination (SEDRIC), a secure cloud-based surveillance system.

The CRF data elements and CRF data collection tool ascertains 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 collects a limited set of information that could be used to identify individual case patients. Local or State public health officials with jurisdictional responsibility 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, are not included in the data collection tool and no other identifying information is transmitted to CDC.

Data will be kept private to the extent allowed by law.

## **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 sex 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. Currently, the average time to complete

the data collection instrument is 15 minutes, including time for reviewing instructions, gathering needed information, and completing the instrument. Therefore, the estimate for burden hours is based on a 15-minute response time.

*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 (Attachment C)	500	1	15/60	125 hours
<b>Total</b>					<b>125 hours</b>

Exhibit 2 shows the estimated annual cost burden associated with individual’s time to participate. We used the 2023 mean average hourly wage for all occupations in the United States. This wage of \$31.48 was obtained from the Bureau of Labor Statistics ([https://www.bls.gov/oes/current/oes\\_nat.htm#00-0000](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 \$3,935.00.

*Exhibit 2. Estimated Annual Burden Costs*

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
All occupations in the United States	CryptoNet Case Report Form (Attachment C)	125 hours	\$31.48	\$3,935.00
<b>Total</b>				<b>\$3,935.00</b>

**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 \$12,719 over a one-year period of data collection. Therefore, a three-year collection period is estimated to cost, \$38,157. Exhibit 3 provides a breakdown of the estimated total annual costs.

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Total Average Cost
<b>Epidemiologist – (GS-13);</b> Epi project development and project management,	200	\$44.77	\$8,954.00

data management, data analysis, CryptoNet epi jurisdiction coordination, publication, and dissemination of results			
<b>Microbiologist (GS-12)</b> Laboratory data management, CryptoNet laboratory jurisdiction coordination, and data analysis	100	\$37.65	\$3,765.00
<b>Estimated Total Cost of Information Collection</b>			<b>\$12,719.00</b>

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

The race/ethnicity question and response options were updated to be in line with a new HHS required question format. Additionally, laboratory test options were updated based on historical data and current testing technologies. These changes do not impact response time.

**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. Basic descriptive analyses will be conducted within SEDRIC using built-in analytic tools. Additional descriptive and univariate analyses will be conducted using statistical software like SAS and R. All data collected and databases will be housed in SEDRIC, a secure cloud-based system on CDC’s network. For non-SEDRIC analytic projects, data will be exported from SEDRIC and stored on a secured 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\_2024 version
- D. Determination of Non-Applicability of Human Subjects Regulations
- E. Privacy Impact Assessment (PIA)

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