



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

Print Date: 10/24/24

Title: CryptoNet Case Report Form Amendment 1

Project Id: 0900f3eb824754b2

Accession #: NCEZID-DWASHEPI-1/20/21-7d96e

Project Contact: Amy L Freeland

Organization: NCEZID/DFWED/WDPB

Status: **Pending Clearance : Amendment**

Intended Use: **Project Determination**

Estimated Start Date: 01/03/2022

Estimated Completion Date: 01/31/2028

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #: 0920-1360

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research - Public Health Surveillance <i>45 CFR 46.102(1)(2)</i>	10/24/24	Peterson_James M. (iy1) CIO HSC
PRA: PRA Applies		10/24/24	Vice_Rudith (nhr9) OMB / PRA
ICRO: Returned with No Decision		2/17/21	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority:	Standard
Date Needed:	11/30/2024
Priority Justification:	
CDC Priority Area for this Project:	Not selected
Determination Start Date:	10/22/24
Description:	This case report form will collect epidemiologic information on sporadic and outbreak-associated cryptosporidiosis cases for which molecular subtyping has been conducted.
IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission:	No
IMS Activation Name:	Not selected
Submitted through IMS Clearance Matrix:	Not selected
Primary Scientific Priority:	Not selected
Secondary Scientific Priority (s):	Not selected
Task Force Responsible:	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	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 cases, clusters, or outbreaks.
Objective:	Administration of the CRF is to conduct surveillance on exposures associated with Cryptosporidium cases 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 management, 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.
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?:	Yes
Activities or Tasks:	New Collection of Information, Data, or Biospecimens
Target Populations to be Included/Represented:	General US Population
Tags/Keywords:	Cryptosporidiosis ; Public Health Surveillance ; Risk Factors
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:	Individual Interview (Quantitative); Individual Interviews (Qualitative); Outbreak Investigation; Surveillance Support
Methods:	Cases, Clusters, and Outbreaks: The CRF will be administered by state and local public health officials via telephone interviews with cases of cryptosporidiosis, or their proxy, who meet the following definitions: Multi-state cluster or outbreak: Multi-state clusters are defined as at least two cases of cryptosporidiosis from different states that are either molecularly related or epidemiologically related. Multi-state clusters and outbreaks are identified in multiple ways, including, but not limited to: through CryptoNet laboratory molecular subtyping, states reaching out to CDC for technical assistance, and through media scans. Single-state cluster or outbreak: Single-state cluster or outbreaks are defined as at least two cases of cryptosporidiosis from the same state that are either molecularly related or epidemiologically related. Single state clusters and outbreaks are identified in multiple ways, including, but not limited to: through CryptoNet laboratory molecular subtyping, states reaching out to CDC for technical assistance, and through media scans. Non-outbreak associated cases: Non-outbreak-associated cases are defined as a cryptosporidiosis cases with no known molecular or epidemiological association to another cryptosporidiosis case. Non-outbreak-associated cases 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. Participants: Respondents will be cryptosporidiosis cases that meets one of the aforementioned definitions, or their proxy. Participation in the interview is voluntary. Recruitment: Officials in state and local public health departments will contact laboratory confirmed cryptosporidiosis cases that

meet one of the aforementioned definitions, or their proxy, to conduct the interviews. CRF Content: The CRF contains questions on the following content areas that would allow for characterizing the case and for identifying possible modes of transmission and exposure settings of importance. This includes: (1) Associated IDs for other surveillance systems, (2) Demographics characteristics, (2) Laboratory testing information, and (3) Symptom onset and exposure information. Specific exposure areas of the CRF include: (1) Recent travel, (2) Recreational water contact, (2) Drinking water source, (4) Consumption of raw or unpasteurized foods and beverages, (5) Recent large gatherings, (6) Childcare exposures, (7) Animal contacts and contact with animal environments, and (8) Recent sexual encounters. The CRF collects limited personally identifiable information (PII). PII collected in the form includes case age, sex, race, ethnicity, and county of residence. The collection of this PII is important to identify whether disparities among subpopulations of cases exist and to ensure prevention and control measures can be tailored to specific subpopulations. The CRF was developed based on subject matter expertise of CryptoNet and Case Surveillance node staff and was reviewed by staff in the WDPB. Sampling: No sampling will be involved in the administration of the CRF. Officials in state and local public health departments will contact cases of cryptosporidiosis, or their proxies, who meet the aforementioned definitions to ask if they would be willing to complete the CRF. Incentives: No incentives will be provided to individuals completing the CRF.

Collection of Info, Data or Biospecimen:

The CRF will be administered by state and local public health officials via telephone interviews with cases of cryptosporidiosis, or their proxy, who meets the aforementioned definitions. Collection of the CRF data elements will primarily employ standardized, quantitative methods. Minimal qualitative methods will be used to elicit additional information about potential exposures from respondents. For example, when case reports traveling outside their home state, the interviewer would ask about the specific travel destination(s), dates of the travel, and any specific events the case participated in while traveling. There are no research questions addressed through this data collection activity. Standardized data will be compiled on recent exposures related to cryptosporidiosis to inform prevention and control efforts. Data will be used to inform case, cluster, and outbreak 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 management, analyses, and dissemination of information collected with the CRF.

Expected Use of Findings/Results and their impact:

Administration of the CRF is to conduct surveillance on exposures associated with Cryptosporidium cases to better inform prevention and control strategies for these infections as well as clusters and outbreaks. There are no research questions addressed; standardized data will be compiled on recent exposures related to cryptosporidiosis cases and outbreaks. 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. Aggregated summaries of CRF findings to describe epidemiologic trends and outbreak investigations will be shared routinely, including CryptoNet state calls and internal CDC meetings. Additionally, aggregated summaries of CRF findings may be shared externally through conference presentations and peer-reviewed journal articles to describe epidemiologic trends, outbreak investigation activities, and prevention and control strategies. Staff in CryptoNet and the Case Surveillance node in WDPB will oversee data analyses and dissemination of information collected with the CRF unless an agreement is made with a state or local health department official.

- Could Individuals potentially be identified based on Information Collected?** Yes
- Will PII be captured (including coded data)?** Yes
- Does CDC have access to the identifiers (including coded data)?:** Yes
- Is this project covered by an Assurance of Confidentiality?** No
- Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?** No
- Is there a formal written agreement prohibiting the** No

release of identifiers?

Funding

Funding yet to be added

HSC Review

Regulation and Policy

Do you anticipate this project will require review by a CDC IRB or HRPO? No

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 wavers

Informed consent for adults No Selection

Children capable of providing assent No Selection

Parental permission No Selection

Alteration of authorization under HIPAA 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 identifiable 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

Will you be working with an outside Organization or Institution? Yes

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	CITI Good Laboratory Practice Exp. Date	Staff Role	Email	Phone	Organization
Amy Freeland	12/19 /2026		09/08/2026			Project Coordinator	igc3@cdc.gov	--	Waterborne Disease Prevention Branch
Colleen Lysen	07/13 /2026	07/30/2023				Co-Investigator	vqy1@cdc.gov	404-639-4654	VIRAL SURVEILLANCE AND DIAGNOSTIC BRANCH
Erin Imada	03/17 /2026					Principal Investigator	ioo6@cdc.gov	404-498-5422	Domestic WASH Epi Team
Jasen Kunz	06/26 /2026					Co-Investigator	izk0@cdc.gov	770-488-7056	Domestic WASH Epi Team
Matthew Seabolt	07/31 /2026					Program Lead	ngr8@cdc.gov	404-718-4163	Waterborne Disease Prevention Branch

Data

DMP

Proposed Data Collection Start Date: 1/3/22

Proposed Data Collection End Date: 1/31/28

Proposed Public Access Level: Public

Public Access Justification:

Data are public health surveillance data. Aggregated summaries of data obtained through this data collection will be released annually to inform annual trends in exposures and other risks of cryptosporidiosis. On a per request basis, data may also be released to researchers after ensuring all potentially personally identifiable information has been removed or aggregated sufficiently to ensure protection of case-patient identity.

How Access Will Be Provided for Data:

Data will be securely stored on an Access database stored on a restricted network drive housed behind the CDC firewall. Aggregated summaries to be published annually will contain no line-level personally identifiable information and case counts will not be presented at a geographic level below the county. Case counts less than five will be masked at the county level. For data released to researchers, line list data may be provided so long as no personally identifiable information is requested. All data will be reviewed to ensure no personally identifiable information is released to the data requestor.

Plans for Archival and Long Term Preservation:

No paper-based CRFs will be maintained long-term. After entering the forms into the Access database stored behind the CDC firewall, they will be destroyed.

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

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
Current	Freeland_Amy L. (igc3) Project Contact	10/22/2024	Public health surveillance.	HS Research Determination Memo	021021ZM-NR-signed.pdf
Current	Freeland_Amy L. (igc3) Project Contact	10/22/2024	The CRF has removed the DOB data element and will only collect age. Let me know if other changes are needed to the CRF.	Data Collection Form	CryptoNet form 2021.docx
Current	Freeland_Amy L. (igc3) Project Contact	10/22/2024	Updated CryptoNet Case Report Form, with updated (1) race /ethnicity question for compliance with new HHS requirements, and (2) lab testing options based on current methodologies /technologies	Other, 0.1260 Request to End Review of Human Research Studies	Att C_CryptoNet Case Report Form_2024 version - CLEAN (1).docx
Current	Freeland_Amy L. (igc3) Project Contact	10/22/2024	This document provides additional information on the proposed data collection.	Other-Project proposal	Project Proposal_CryptoNet_01.13.2021.docx
Current	Freeland_Amy L. (igc3) Project Contact	10/22/2024	This is the CryptoNet Case Report Form for which we are seeking approval. These data will complement molecular subtyping data obtained from laboratory testing of specimens collected from the same case.	Data Collection Form	CryptoNet form 2019.pdf
	Peterson_James M. (iy1) CIO HSC	02/10/2021	Public health surveillance.	HS Research Determination Memo	021021ZM-NR-signed.pdf
	Marsh_Zachary (ksf6) Division Approver Projects	02/04/2021	The CRF has removed the DOB data element and will only collect age. Let me know if other changes are needed to the CRF.	Data Collection Form	CryptoNet form 2021.docx
	Marsh_Zachary (ksf6) Project Contact	01/20/2021	This document provides additional information on the proposed data collection.	Other-Project proposal	Project Proposal_CryptoNet_01.13.2021.docx
	Marsh_Zachary (ksf6)	01/20/2021	This is the CryptoNet Case Report Form for which we are seeking approval. These data will complement molecular subtyping	Data Collection Form	CryptoNet form 2019.pdf

	Project Contact	data obtained from laboratory testing of specimens collected from the same case.		
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