CryptoNet Case Report Form

Request for OMB approval of a New Information Collection Instrument

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Supporting Statement B

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1. Respondent Universe and Sampling Methods

There will be no statistical methods used to select respondents for this data collection. Interviews will be conducted with cases of cryptosporidiosis, or their proxy, who meet the following definitions: (1) Multi-state cluster or outbreak: Multi-state clusters and outbreaks are defined as at least two cases of cryptosporidiosis from different states that are either molecularly- or epidemiologically-related, respectively. 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; (2) Single-state cluster or outbreak: Single-state clusters or outbreaks are defined as at least two cases of cryptosporidiosis from the same state that are either molecularly- or epidemiologically-related, respectively. 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; or (3) 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.

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.

2. Procedures for the Collection of Information

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 proxies, who meet one of the aforementioned definitions.

Participants: Respondents will be cryptosporidiosis cases that meet one of the aforementioned definitions, or their proxies. Participation in the interview is voluntary.

Recruitment: Officials in state and local public health departments will contact laboratory confirmed cryptosporidiosis cases, or their proxies, that meet one of the aforementioned definitions 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 includes a limited set of questions asking for personally identifiable

information (PII), including age, sex, race, ethnicity, and county of residence. 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.

Data collection: The CRF will be administered by state and local public health officials via telephone interviews with cases of cryptosporidiosis, or their proxies, 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.

Form transmission: The completed CRF will be shared with CDC via encrypted email or through facsimile with email being the preferred means to share.

3. Methods to Maximize Response Rates and Deal with No Response

In general, state and local public health officials will make every effort to contact identified, laboratory confirmed cryptosporidiosis cases, as resources allow. Policies vary, but many jurisdictions attempt to contact a case at least three times before deeming them 'lost to follow-up'. The CRF is designed to be administered in approximately 15 minutes via telephone interview, so the burden on cases to complete the interview should be sufficiently low to maximize response rates.

4. Tests of Procedures or Methods to be Undertaken

The estimate for burden hours is based on a pilot test of the data collection instrument by two 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.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data:

Individuals consulted on statistical aspects of the design: not applicable.
The CRF was developed based on subject matter expertise of CryptoNet and the Case Surveillance node staff in WDPB (listed below). Data will be analyzed by CryptoNet and the Case Surveillance node staff in CDC's Waterborne Disease Prevention Branch.

Individuals collecting and/or analyzing data:
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