

DFWED National Hypothesis Generation and Investigation Module

Request for OMB approval of a New Information Collection

01/14/2025

Supporting Statement A

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- **Goal of the study:** The goal of the DFWED National Hypothesis Generation and Investigation Module is to define a core set of standardized data elements and forms used for outbreak investigations and surveillance activities for a variety of enteric illnesses. These investigations include patients with an identified antimicrobial-resistant illness and cases associated with a multistate cluster or outbreak investigation.
- **Intended use of the resulting data:** The DFWED National Hypothesis Generation Investigation Module will be used by federal, state, and local public health officials responsible for conducting interviews with reported cases of enteric disease in their jurisdiction in order to systematically assess exposure elements and risk factors during an investigation of interest.
- **Methods to be used to collect:** The data collection instruments and forms were designed for administration via telephone interviews or electronic submission.
- **The subpopulation to be studied:** The ill individuals or their designated proxy, identified as part of an investigation of interest.
- **How data will be analyzed:** Descriptive analyses and univariate analyses of exposures among cases interviewed as part of the investigation of interest.

1. Circumstances Making the Collection of Information Necessary

This is a new Information Collection Request. We are requesting an approval for a period of 3 years. This new request includes revisions of previously approved hypotheses generation investigation forms currently approved under OMB Control Numbers 0920-0997 and 0920-1307 in addition to new investigation forms. To limit the number of hypothesis generation questionnaires, we aimed to develop a cross cutting information collection package to increase data sharing within our division and reduce data collection redundancies.

The Division of Foodborne, Waterborne, and Environmental Diseases ([DFWED](#)) at the Centers for Disease Control and Prevention (CDC) aims to protect public health through the prevention and control of disease, disability, and death caused by foodborne, enteric, waterborne, and environmentally transmitted infections. DFWED is comprised of five branches, Enteric Diseases Epidemiology Branch (EDEB), Enteric Diseases Laboratory Branch (EDLB), Mycotic Diseases Branch (MDB), Outbreak Response and Prevention Branch (ORPB), and Waterborne Disease Prevention Branch (WDPB). These branches all work collaboratively to conduct enteric foodborne, waterborne, and zoonotic disease surveillance and outbreak investigations. ORPB works with local, state, and federal public health partners to ensure rapid and coordinated surveillance, detection, and response to multistate foodborne and zoonotic outbreaks. This work is to limit the number of illnesses and to learn how to prevent similar outbreaks from happening in the future. The Shigella Prevention and Control (SPC) Program is a sub-unit within EDEB that focuses on the prevention and control of shigellosis in the United States. The SPC Program's current scope of work includes leading cluster and outbreak investigations, and they collaborate with other groups in DFWED and in other centers that engage in Shigella-related activities. The National Antimicrobial Resistance Monitoring System (NARMS) is a national public health surveillance system that tracks antimicrobial resistance in enteric bacteria that are transmitted through food, the environment, animal, and person-to-person (including sexual) contact. NARMS created the

Select Isolates Response Initiative (SIRI) to collect additional exposure data on a variety of enteric pathogens that have concerning antimicrobial resistance. These CDC programs across DFWED work with state, territorial, local and tribal (STLT) public health partners to ensure rapid and coordinated surveillance, detection, and investigation, and response to enteric foodborne, waterborne, and zoonotic illnesses and outbreaks.

Changes in society, technology, our environment, and microorganisms themselves are affecting the occurrence and complexity of enteric foodborne, waterborne, and zoonotic diseases. DFWED programs conduct disease surveillance and outbreak response for several pathogens including *Campylobacter*, *Listeria monocytogenes*, *Salmonella*, Shiga-Toxin producing *E.coli* (STEC), *Shigella*, *Vibrio*, and *Cronobacter* infections in infants. To overcome challenges presented by the changing landscape of enteric diseases, the need for comprehensive hypothesis generating questionnaires focused on a range of settings, activities, and potential modes of transmission are essential to guide prevention and control activities. For example, person-to-person contact is the most common mode of transmission for shigellosis, and as shigellosis is highly contagious, it can be challenging to identify how individuals could have become ill. Additionally, antimicrobial resistance is one of our most serious health threats, and enhanced surveillance is critical to detect the emergence and spread of antibiotic resistance. To streamline data collection for shigellosis, a single form is proposed to collect both exposure information and antibiotic resistance details.

To increase data interoperability, reduce redundancies, and improve cross-division coordination, programs across DFWED developed the following streamlined collection instruments.

Form 1. National Hypothesis Generation Questionnaire (NHGQ) defines a core set of data elements to be used for hypothesis generation once a cluster of illnesses is determined to be a multistate foodborne or zoonotic outbreak investigation. NHGQ-defined elements would be used in the early phases of an outbreak investigation to generate hypotheses about the source(s) of infection and facilitate collaboration across jurisdictions. This form is currently approved under OMB Control Number 0920-0997 but will be moved to this ICR upon OMB approval.

Form 2. Foodborne Focus Questionnaire – Once a leading hypothesis is identified during the hypothesis generation phase, typically after no more than 15 to 20 interviews using the NHGQ, more specific information needs to be collected, such as type, variety, brand, and purchase location, to confirm the hypothesis. During these later phases of an outbreak investigation, the NHGQ is no longer used. Data collected through the Foodborne Focus Questionnaire are utilized to tailor the next phase of the outbreak investigation and guide potential public health action, such as a product recall or public health alert. DFWED would only deploy sections relevant to the suspected foods or food categories identified in the hypothesis generation phase.

Form 3. Animal Contact Focus Questionnaire – This questionnaire will be deployed once a suspected vehicle is identified either via the NHGQ or via epidemiologic data collected in initial STLT patient interviews. DFWED would only deploy sections relevant to the species identified as the potential outbreak vehicle. This questionnaire would be used to confirm the hypothesized animal vehicle, to collect information needed to take public health action including animal contact settings, purchase

locations, and pet food brands and lot numbers, and to identify risk communication priorities so we can instruct the public how to prevent further illnesses.

Form 4. Shigella National Hypothesis Generation Questionnaire – Questionnaire is used for multistate outbreaks of Shigellosis. Shigellosis is highly contagious, and as person-to-person transmission is coming, it can be challenging to identify how individuals could have become ill. As a result, a comprehensive hypothesis generating questionnaire focused on a range of settings, activities, and potential modes of transmission are needed to guide prevention and control activities. This form is currently approved under OMB Control Number 0920-1307 but will be moved to this ICR upon OMB approval.

Form 5. NARMS SIRI Module 1 (nontyphoidal *Salmonella*, STEC, *Vibrio*, or *Campylobacter*) – this questionnaire module includes questions that will be asked of patients with nontyphoidal *Salmonella*, STEC, *Vibrio*, or *Campylobacter* isolates that have concerning antimicrobial resistance. The questions will be used to characterize exposures, risk factors, and sources of illness for resistant enteric infections to inform efforts to prevent additional infections and the spread of disease.

Form 6. NARMS SIRI Questionnaire Module 2 (nontyphoidal *Salmonella* except multidrug-resistant Newport, STEC, or *Vibrio*) – this questionnaire module includes questions that will be asked of patients with nontyphoidal *Salmonella* (except serovar Newport), STEC or *Vibrio* isolates that have concerning antimicrobial resistance. The questions will be used to characterize exposures, risk factors, and sources of illness for resistant enteric infections to inform efforts to prevent additional infections and the spread of disease.

Form 7. NARMS SIRI Questionnaire Module 3 (multidrug-resistant *Salmonella* Newport) – this questionnaire module includes questions that will be asked of patients with multidrug-resistant *Salmonella* Newport isolates. The questions will be used to characterize exposures, risk factors, and sources of illness for resistant enteric infections to inform efforts to prevent additional infections and the spread of disease.

Form 8. NARMS SIRI Questionnaire Module 4 (*Campylobacter*) – this questionnaire module includes questions that will be asked of patients with *Campylobacter* isolates that have concerning antimicrobial resistance. The questions will be used to characterize exposures, risk factors, and sources of illness for resistant enteric infections to inform efforts to prevent additional infections and the spread of disease.

Form 9. NARMS SIRI Questionnaire Module 5 (Typhoid or Paratyphoid) – this questionnaire module will be asked of patients with *Salmonella* Typhi or Paratyphi isolates that have concerning antimicrobial resistance. The questions will be used to characterize exposures, risk factors, and sources of illness for resistant enteric infections to inform efforts to prevent additional infections and the spread of disease.

Authorizing Legislation for data collection comes from Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment 1).

2. Purpose and Use of Information Collection

The information collection forms will be used by federal, state, and local public health officials responsible for conducting interviews with cases of enteric disease who are part of an enteric disease cluster or outbreak or have bacterial isolates with antimicrobial resistance.

Cluster and Outbreaks: The forms will be administered by STLT public health officials via telephone interviews or self-administered web-based surveys with cases or their proxy who are part of an enteric disease cluster or outbreak that meets the following definitions: (1) *Multistate cluster or outbreak:* Multistate clusters are defined as at least two confirmed illnesses from different states that are genetically related. Multistate clusters and outbreaks are identified in multiple ways, including, but not limited to: through PulseNet, the national molecular subtyping and surveillance network coordinated by CDC, states reaching out to CDC for technical assistance, and through media scans. (2) *Single state cluster or outbreak:* Single state cluster or outbreaks are defined as at least two cases of an illness from the same state that are either genetically related or epidemiologically related. Single state clusters and outbreaks are identified in multiple ways, including, but not limited to: through PulseNet, state surveillance and cluster detection, states reaching out to CDC for technical assistance, and through media scans.

Antimicrobial Resistance: The forms will be administered by STLT public health officials via telephone interviews or self-administered web-based surveys with cases or their proxy of nontyphoidal *Salmonella*, STEC, *Vibrio*, or *Campylobacter* whose bacterial isolates have concerning antimicrobial resistance. These cases are identified by the National Antimicrobial Resistance Monitoring System (NARMS).

CDC's ORPB has used the NHGQ (Form 1) during multistate outbreak investigations for over a decade, ensuring the utility of the data collection. The data elements of the NHGQ have been used voluntarily by STLT public health partners engaged in multistate outbreak investigations. Since the renewal of the NHGQ in 2019, ORPB has investigated over 470 multistate foodborne and zoonotic outbreaks involving over 26,000 ill people. An outbreak vehicle was identified in 199 of these investigations. These outbreaks led to product recalls and regulatory actions that removed millions of pounds of contaminated products out of commerce. In almost all instances, the NHGQ or iterations of the NHGQ have been instrumental in the successful investigation of these outbreaks. The NHGQ allowed investigators to efficiently and effectively interview ill people as they are identified. Because these exposures are captured in a common, standard format, investigators can share and analyze data rapidly across jurisdictions. Faster interview response and analysis times allowed for rapid epidemiologic investigations and quicker regulatory action, preventing thousands of additional illnesses from occurring and spurring industry to adopt and implement new food safety measures in an effort to prevent future outbreaks.

With the evolving landscape of enteric diseases, the need for comprehensive hypothesis generating questionnaires focused on a range of settings, activities, and potential modes of transmission are essential to guide prevention and control activities. The hypothesis generating questionnaires are needed to fill an identified gap of no standardized method for ascertaining core exposures among cases of enteric disease. Without the forms proposed within this package, hypothesis-generating data collection instruments must be designed for each investigation. This results in delayed data collection and analysis, which in turn, delays epidemiologic investigations and limits the ability of public health officials to take necessary public health actions. Use of these forms will improve timeliness during the hypothesis-

generating phase of investigations, thereby shortening the time to implementation of public health measures.

3. Use of Improved Information Technology and Burden Reduction

The data elements and forms were designed for administration by STLT public health officials via telephone interviews or self-administered web-based surveys with cases or their proxies. Forms 1-4 are available in Epi-Info, a developed electronic data collection survey that allows the interviewer to submit completed interview data through secure electronic transmittal. The data are ingested by the Data Collection and Integration for Public Health Event Response (DCIPHER), a secure, cloud-based surveillance platform. The System for Enteric Disease Response, Investigation, and Coordination (SEDRIC) is DFWED's module in DCIPHER which allows CDC to seamlessly integrate epidemiologic and laboratory data in real-time during response to enteric foodborne, waterborne, and zoonotic illnesses and outbreaks. Each form proposed within this package will be available to submit directly within SEDRIC by STLT public health officials. The use of electronic data collection and secure integration limits the burden of needing to enter data from a paper-based forms submitted via facsimile into an electronic format.

4. Efforts to Identify Duplication and Use of Similar Information

The purpose of this OMB package is to reduce data collection redundancies and improve data harmonization across DFWED. The submitted forms standardize hypothesis generating instruments used during enteric disease outbreak investigations and surveillance. This includes foodborne, waterborne, and zoonotic disease surveillance and outbreak investigations. In addition, enhanced surveillance for antibiotic resistant isolates is also included in this package.

Similar information may be collected on state or local standardized case report forms. The specific variables included in this information collection request are not included in any other nationwide disease-specific surveillance system.

Form 1 – CDC conferred with internal and external partners through various workgroups and meetings. The NHGQ should not generally lead to collection of duplicate information: the NHGQ can be populated with any data elements routinely collected by the state or local jurisdiction on standardized infectious disease case report forms during their initial investigation. The *Listeria* Initiative Case Report Form (OMB Control No. 0920-0004) provides a similar function but is designed for use for all cases of listeriosis and as such, only collects data specific to the unique exposures of importance for infection with *Listeria monocytogenes*. The NHGQ does not duplicate or replicate the *Listeria* Initiative Case Report Form. Instead, it provides data for the vast array of potential exposures of importance for investigating multistate outbreaks of various enteric disease pathogens.

Form 2. The Foodborne Focus Questionnaire is used for multistate outbreaks of *Salmonella*, STEC, *Listeria monocytogenes*, and *Campylobacter*. It is designed to collect specific data on food exposures after a suspect vehicle is identified using the NHGQ. Questions on the Foodborne Focus Questionnaire

are not redundant of the NHGQ but ask questions to get at specific details like type, variety, brand, how a product was purchased, and how a product was consumed. These specific data are used to help guide further investigation and regulatory action in multistate foodborne outbreaks.

Form 3. The Animal Contact Focus Questionnaire is used for zoonotic multistate outbreaks of *Salmonella*, STEC, *Listeria monocytogenes*, and *Campylobacter*. It is designed to collect specific data on animal exposures after a suspect vehicle is identified. Questions on the Animal Contact Focus Questionnaire are not redundant of the NHGQ but ask questions to get at specific details like animal breeds, brand and lot numbers of feed, animal contact setting, and animal purchase location. These specific data are used to help guide further investigation and public health action in multistate zoonotic enteric disease outbreaks.

Form 4. The *Shigella* National Hypothesis Generation Questionnaire is the only national, standardized hypothesis generating interview data collection instrument for use during single or multistate shigellosis cluster or outbreak investigations. The information gathered through the SHGQ is not available from other data sources or through other means. Prior to developing the *Shigella* investigation form in 2020, WDPB staff consulted with both internal and external stakeholders to confirm that this effort is not duplicative.

Forms 5–9. The NARMS SIRI questionnaire modules are used when patients are not part of multistate outbreaks, but their isolates have concerning antimicrobial resistance. It is designed to characterize exposures, risk factors, and sources of illness for resistant enteric infections to inform efforts to prevent additional infections and the spread of disease. Questions on the NARMS SIRI questionnaire modules are not duplicative: the NARMS SIRI questionnaire modules can be populated with any data elements routinely collected by the state or local jurisdiction on standardized infectious disease case report forms during their initial investigation. Patients completing the NARMS SIRI questionnaire modules are not usually part of an outbreak and would not otherwise complete an additional questionnaire.

5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently

The data collection proposed in this ICR are for use during single or multistate cluster or outbreak investigations, or illnesses with concerns of antibiotic resistance. Collecting the data less frequently would impact efforts to identify the source of exposure to guide further investigation and public health action.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

A. A 60-day Federal Register Notice was published in the *Federal Register* on April 5, 2024, vol. 89, No. 67, pp. 24004 (Attachment 2). CDC did receive public comments related to this notice. Two public comments were received. Neither comment was substantive. Neither comment addressed the content of the proposed forms. Generic template responses were provided in response to the comments (Attachment 12).

B. Forms 1-2. Public health partners from across the U.S., both internal and external to CDC, participated in the development process including the Food and Drug Administration and the Department of Agriculture. Every six years, a workgroup of federal, state, and local public health partners directly involved in multistate foodborne and zoonotic outbreak investigations are convened to review the relevance and usefulness of data elements collected on the NHGQ. This data collection instrument is a direct result of these collaborations.

Forms 3-9. 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

CDC's Information Systems Security Officer reviewed this submission and determined that the Privacy Act does apply. A Privacy Impact Assessment is included as part of this submission (Attachment 13).

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.

These data collection tools will ascertain information from respondents about exposures (food, water, travel, and other) preceding the onset of illness. It will not collect any information that could be used to identify individual patients. STLT public health officials with jurisdictional responsibility will maintain the respondent's name, telephone number, and other personally identifiable information. This information will not be included in the data collection tool and no identifying information will be 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)

NCEZID's Human Subjects Advisor has determined that information collection is not research involving human subjects. IRB approval is not required. (Attachment 14-15).

Justification for Sensitive Questions

Shigella and *Campylobacter* bacteria can be spread in multiple ways. This includes through contaminated food and water, and via sexual and non-sexual person-to-person contact. To determine if cases became ill via sexual person-to-person contact, case patients interviewed with Forms 4 and 8 will be asked questions about sexual activity and behavior, sexual partners, drug and alcohol use during sexual activity, and previous diagnosis with a sexually transmitted infection. To inform prevention and control efforts, questions about sexual orientation will also be asked to characterize the demographics of case patients. As part of this module, case patients are given an explanation for why the sensitive questions are asked and are provided the option to opt out of answering these questions.

In addition to sexual health related questions, other potentially sensitive questions are asked of case patients. This includes questions related to insecure housing, homelessness, and family income. These questions are asked because people experiencing homelessness have been identified as a risk population, and poverty has been identified as a risk factor for *Shigella* infection.

All questions for all forms are optional, and patients can choose to answer the questions they feel comfortable responding to.

12. Estimates of Annualized Burden Hours and Costs

Form 1-2. Interviews will be conducted with cases of enteric disease identified as part of a multistate outbreak investigation. Based on the estimated number of cases of foodborne disease in the U.S. and the proportion of those cases that are outbreak associated, it is estimated that the hypothesis generation forms would be administered to approximately 4,000 individual respondents across all jurisdictions each year. The estimate for burden hours is based the previous three years of data collection using Form 1 under their initial OMB approval.

Form 3. Based on the estimated number of cases of enteric disease from animal contact in the U.S. and the proportion of those cases that are outbreak associated, it is estimated that the hypothesis generation forms would be administered to approximately 450 individual respondents across all jurisdictions each year.

Form 4. Based on the estimated number of cases of shigellosis in the U.S. and the proportion of those cases that are cluster or outbreak associated, the SHGQ is administered to approximately 1500 individual respondents across all jurisdictions each year. The estimate for burden hours is based the previous three years of data collection using Form 4 under their initial OMB approval.

Form 5. - Form 9. Based on the estimated number of cases of enteric disease with antimicrobial resistance patterns identified in the U.S., the four forms will be administered to approximately 660 individual respondents across all jurisdictions each year.

The average time to complete the instruments including time for reviewing instructions, gathering needed information and completing the instrument were used for estimating burden hours. This data collection uses qualitative methods, including telephone interviews guided by semi-structured protocols designed to elicit core elements exposures from respondents.

Exhibit 1 shows the estimated annual burden hours for each organization’s time to participate in this research. The total annual burden is estimated to be 5,850 hours.

Exhibit 1

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Cluster and outbreak case patients	NHGQ (Form 1)	4,000	1	45/60	3,000 hrs.
Cluster and outbreak case patients	Foodborne Focus Questionnaire (Form 2)	4,000	1	20/60	1,333 hrs.
Cluster and outbreak case patients	Animal Contact Focus Questionnaire (Form 3)	450	1	30/60	225 hrs.
Cluster and outbreak case patients	Shigella Hypothesis Generating Questionnaire (Form 4)	1500	1	45/60	1,125 hrs
Nontyphoidal <i>Salmonella</i> , STEC, <i>Vibrio</i> , or <i>Campylobacter</i> case patients whose bacterial isolates have concerning	NARMS SIRI Questionnaire Module 1 (Form 5)	305	1	15/60	76 hrs.

antimicrobial resistance					
Nontyphoidal <i>Salmonella</i> (except Newport strain), STEC, or <i>Vibrio</i> case patients whose bacterial isolates have concerning antimicrobial resistance	NARMS SIRI Questionnaire Module 2 (Form 6)	130	1	10/60	22 hrs.
Multidrug-resistant <i>Salmonella</i> Newport case patients	NARMS SIRI Questionnaire Module 3 (Form 7)	125	1	15/60	31 hrs.
<i>Campylobacter</i> case patients whose bacterial isolates have concerning antimicrobial resistance	NARMS SIRI Questionnaire Module 4 (Form 8)	50	1	25/60	21 hrs.
<i>Salmonella</i> Typhi or Paratyphi case patients whose bacterial isolates have concerning antimicrobial resistance	NARMS SIRI Questionnaire Module 5 (Form 9)	50	1	20/60	17 hrs.
Total					5,850

B. Estimated Annualized Burden Costs

We used the 2023 mean average hourly wage for all occupations in the United States. This wage of \$31.48 was obtained from the [Department of Labor website](#).

Exhibit 2 shows the estimated annual burden hours for each organization to participate in the information collection forms. The total annual burden is estimated to be \$184,221.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General Public	NHGQ (Form 1)	3,000	\$31.48	\$94,440
General Public	Foodborne Focus Questionnaire (Form 2)	1,333	\$31.48	\$41,962
General Public	Animal Contact Focus Questionnaire (Form 3)	225	\$31.48	\$7,083
General Public	Shigella Hypothesis Generating Questionnaire (Form 4)	1125	\$31.48	\$35,415
General Public	NARMS SIRI Questionnaire Module 1 (Form 5)	76	\$31.48	\$2,392
General Public	NARMS SIRI Questionnaire Module 2 (Form 6)	22	\$31.48	\$693
General Public	NARMS SIRI Questionnaire Module 3 (Form 7)	31	\$31.48	\$976
General Public	NARMS SIRI Questionnaire Module 4 (Form 8)	21	\$31.48	\$661
General Public	NARMS SIRI Questionnaire Module 5 (Form 9)	17	\$31.48	\$535
Total				\$184,157

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

There are no costs to respondents other than their time to participate.

14. Annualized Cost to the Government

The estimated total cost to the Federal Government for this project is \$161,061 annually. Exhibit 3 provides a breakdown of the estimated total costs.

Exhibit 3

Estimated Annualized Cost to the Government per Activity – NHGQ (Form 1)	
Cost Category	Estimated Annualized Cost
Salary	\$29,520
Methods: One epidemiologist at a GS-9 Step 1 hourly rate of \$24.60 multiplied by the annual burden hours of administrating and analyzing NHGQ (1,200) equals \$29,520 per year.	
Estimated Annualized Cost to the Government per Activity – Foodborne Focus Questionnaire (Form 2)	
Cost Category	Estimated Annualized Cost
Salary	\$55,596
Methods: One epidemiologist at a GS-9 Step 1 hourly rate of \$24.60 multiplied by the annual burden hours of administrating and analyzing the Foodborne Focus Questionnaire (2,260) equals \$55,596 per year.	
Estimated Annualized Cost to the Government per Activity – Animal Contact Focus Questionnaire (Form 3)	
Cost Category	Estimated Annualized Cost
Salary	\$22,297
Methods: One epidemiologist at a GS-13 Step 1 hourly rate of \$49.55 multiplied by the annual burden hours of administering and analyzing the Animal Contact Focus Questionnaire (450) equals \$22,297 per year.	
Estimated Annualized Cost to the Government per Activity – Shigella Hypothesis Generating Questionnaire (Form 4)	
Cost Category	Estimated Annualized Cost
Salary	\$36,900
Methods: One epidemiologist at a GS-9 Step 1 hourly rate of \$24.60 multiplied by the annual burden hours of administrating and analyzing the Foodborne Focus Questionnaire (1,500) equals \$36,900 per year.	
Estimated Annualized Cost to the Government per Activity – NARMS SIRI Questionnaire (Forms 5–9)	
Cost Category	Estimated Annualized Cost
Salary	\$16,748
Methods: One epidemiologist at a GS-13 Step 1 hourly rate of \$49.55 multiplied by the annual burden hours of administrating and analyzing the NARMS SIRI Questionnaire Modules (338) equals \$16,748 per year	

15. Explanation for Program Changes or Adjustments

This is a new information collection. For two existing forms with OMB approvals OMB Control Numbers 0920-0997(Form 1) and 0920-1307 (Form 4) – race and ethnicity data collection were updated to meet the new OMB standards. In Form 4, data variables were standardized to be homogenous with the other collection forms in this package.

16. Plans for Tabulation and Publication and Project Time Schedule

This new data collection will use qualitative methods, including telephone interviews guided by semi-structured protocols designed to elicit core elements exposures from respondents. Interviewers will be

able to probe further or deviate from protocols to the extent that respondents reveal new information. There are no specific research questions addressed, but instead, will ascertain standardized data across jurisdictions during multiple multistate investigations.

Project Time Schedule	
Activity	Time Schedule
Utilize the forms to conduct interviews during enteric disease outbreak investigations and surveillance	Months 1-36
Ongoing data analysis	Months 1-36

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

The display of the OMB Expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

1. Authorizing Legislation
2. 60-Day FRN
3. Form 1. National Hypothesis Generation Questionnaire (NHGQ)
4. Form 2. Foodborne Focus Questionnaire
5. Form 3. Animal Contact Focus Questionnaire
6. Form 4. Shigella National Hypothesis Generation Questionnaire
7. Form 5. NARMS SIRI Module 1
8. Form 6. NARMS SIRI Questionnaire Module 2
9. Form 7. NARMS SIRI Questionnaire Module 3
10. Form 8. NARMS SIRI Questionnaire Module 4
11. Form 9. NARMS SIRI Questionnaire Module 5
12. Public Comments and Responses
13. DCIPHER PIA
14. Non-research determination forms 1-4
15. Non-research determination forms 5-9
- 16.