

**Request for Approval Under the Generic Clearance for
Emergency Epidemic Investigation Data Collections
(0920-1011)**

Instruction: This form should be completed by the primary contact person from the CDC CIO that will be sponsoring the investigation.

Determine if your investigation is appropriate for this Generic mechanism: *Instruction: Before completing and submitting this form, determine first if the proposed investigation is appropriate for the EEI Generic ICR mechanism. Complete the checklist below. If you select “yes” to all criteria in Column A, the EEI Generic IR mechanism can be used. If you select “yes” to any criterion in Column B, the EEI Generic ICR mechanism cannot be used.*

Column A	Column B
CDC epidemiological assistance is requested by one or more external partners (e.g., local, state, tribal, military, port, other federal agency, or international health authority or other partner organization). <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	The Investigation is initiated by CDC, without request from an external partner. <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
The investigation is urgent in nature (i.e., timely data are needed to inform rapid public health action to prevent or reduce injury, disease, or death). <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	The investigation is not urgent in nature. <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
The investigation is characterized by undetermined agent, undetermined source, undetermined mode of transmission, or undetermined risk factors. <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	The investigation is conducted for the primary purpose of program evaluation, surveillance, needs assessment, or research to contribute to generalizable knowledge. <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
One or more CDC staff (including trainees and fellows) will be deployed to the field. <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	CDC staff (including trainees or fellows) are not deployed to the field. <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Data collection will be completed in 90 days or less. <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Data collection expected to require greater than 90 days. <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Did you select “Yes” to **all** criteria in Column A?

If yes, the EEI Generic ICR may be appropriate for your investigation. → You may proceed with this form.

Did you select “Yes” to **any** criterion in Column B?

If yes, the EEI Generic ICR is not appropriate for your investigation. → Stop completing this form now.

GenIC # - Date

Title of Investigation: *Instruction: Provide the title of the investigation in the following format: [Undetermined agent, undetermined source, undetermined mode of transmission, undetermined risk factor] for [disease/problem] among [subpopulation]—[State], [Year]*

Location of Investigation: *Instruction: Indicate location where investigation will occur. If multiple locations, specify each one.*

State:
 City/County (if applicable)
 Country

Requesting Agency: *Instruction: Indicate name of agency requesting epidemiological assistance and the name and position title of the requestor*

Agency:
 Name and Position Title:

Note: Attach the Letter of Invitation requesting support. The letter should include the following information: 1) background on the outbreak or event; 2) steps already taken toward prevention and control, if any; 3) request for CDC assistance, including objectives of the investigation; and 4) how data will be used to inform prevention and control measures. Sensitive information in the Letter of Invitation not appropriate for public dissemination should be redacted.

Description of Investigation

1. **Problem to be Investigated:** *Instruction: Provide a summary of the outbreak or event. The summary should include all the information you know at this time about the outbreak or event and the investigation that is planned. At a minimum, please provide the following information: 1) background necessary to understand the importance of the outbreak or event, including a justification of the need for an investigation and why this issue requires an urgent response; 2) the objectives of the investigation, including how the information collected will be used to inform prevention and control measures; and 3) a brief overview of the investigation planned, including study design, respondents, mode of data collection. In the description, indicate whether a data collection instrument is attached with the GenIC request (refer to as Appendix 1, etc) and what instruments will be developed in the field. (suggested length: 250-500 words).*

Shigella is a bacterial pathogen that causes shigellosis, a generally self-limited illness characterized by fever and enteritis. Of the four *Shigella* species, *S. sonnei* is the most common cause of shigellosis in the United States. Due to its low infectious dose, *Shigella* is readily transmitted person-to-person through the fecal-oral route; additional modes of transmission include contaminated food, drinking water, and recreational water. Outbreaks occur year-round; child care facilities are the most common setting. Attention to hygiene, access to safe water, and adequate sanitation are mainstays of prevention.

In 2016, health departments in Genesee County (GCHD) and Saginaw County (SCHD) reported an increase in shigellosis cases over baseline beginning in March. From January 1, 2016 to October 4, 2016, the Michigan Department of Health and Human Services (MDHHS) received reports of 83 cases from GCHD and 47 cases from SCHD. Epidemiologic and laboratory investigations are

needed to identify associated risk factors to inform ongoing prevention efforts.

On October 7, the Michigan Department of Health and Human Services requested CDC assistance to investigate the 2016 outbreak of Shigellosis in Genesee and Saginaw Counties.

The overall objectives of the investigation are to:

1. Determine the magnitude of the outbreak and characterize patient morbidity and mortality (if applicable) in the context of individual-level risk factors (e.g., co-morbidities, access to health care, etc.).
2. Combine epidemiologic data from interviews and molecular data (PFGE and WGS) to 1) identify chains of transmission, 2) determine genetic relatedness of *Shigella* isolates from case-patients, and 3) outline the evolution of the outbreak over time and space.
3. Conduct a case-control investigation to identify risk factors for shigellosis in Genesee and Saginaw Counties; among other factors, water type and water use will be examined.
4. Map existing data related to quality of water from municipal systems (e.g., disinfectant residuals, sewage and water main breaks, triggered positives for total coliforms, and other aspects of water quality) and assess spatial and temporal correlations with incident shigellosis.
5. Assess the need for household water testing among cases and controls based on the results of epidemiologic investigation as outlined in objectives 3 and 4.

Molecular data and municipal water system data will be extracted from existing data sources.

This EEI GenIC seeks OMB approval for the new information collection associated with accomplishing these objectives. Specifically, approval is requested for a case-control investigation conducted to:

1. Determine mode of transmission and risk factors for shigellosis.
2. Develop public health interventions that specifically address risk factors associated with the outbreak.
3. Inform communication and outreach to stakeholders, including community members.
4. Determine whether additional study is indicated.

Information will be collected via a case-control investigation to identify risk factors for shigellosis (Appendix 1: Questionnaire). A random sample of cases (n=75) will be selected from Genesee and Saginaw counties; controls (n=225) will be selected at random from the source population (residents of Genesee and Saginaw Counties). Cases and controls will be contacted by phone. A standardized questionnaire will be administered by trained personnel. Data will be stored on secure servers housed at MDHHS and accessed only via password-protected computers by staff with appropriate clearance and security training.

2. Characteristics of Outbreak or Event (Check all that Apply):

- Undetermined agent
- Undetermined source
- Undetermined mode of transmission
- Undetermined risk factor

3. Respondents: *Instruction: Select all that apply. For each respondent type selected, provide a brief description. Be sure to include a description of control respondents, if applicable. Use as much space as necessary for each description.*

General public (describe):

Members of the general public residing in Genesee and Saginaw Counties will be randomly selected as controls (n=225). For controls who are less than 18 years of age, interviews will be conducted with a parent or legal guardian.

Healthcare staff (describe):

Laboratory staff (describe):

Patients (describe):

A random sample of 75 shigellosis case-patients from Genesee and Saginaw counties will be interviewed. For case-patients who are less than 18 years of age, interviews will be conducted with a parent or legal guardian.

Restaurant staff (describe):

Other (describe):

4. Selection of Respondents: *Instruction: Provide a brief description of how respondents will be identified and selected. Use as much space as necessary for the description.*

Case-patients (n=75) will be selected at random from the Michigan Disease Surveillance System. Controls (n=225) will be recruited at random from the source population, as described above. We anticipate using a random digit dialing program to identify controls.

5. Study Design: *Instruction: Select all that apply. For each study design planned, provide a brief description. Use as much space as necessary for the description.*

Epidemiologic Study (indicate which type(s) below)

Descriptive Study (describe):

Cross-sectional Study (describe):

Cohort Study (describe):

Case-Control Study (describe):

Data will be collected via a case-control investigation to identify risk factors for shigellosis (Appendix 1: Case Questionnaire).

Other (describe):

Environmental Assessment (describe):

Laboratory Testing (describe):

Other (describe):

6. Data Collection Mode: *Instruction: Select all that apply. For each data collection mode planned, provide a brief description. Use as much space as necessary for the description.*

Survey Mode (indicate which mode(s) below):

Face-to-face Interview (describe):

Telephone Interview (describe):

Cases and controls will be contacted and interviewed by phone.

Self-administered Paper-and-Pencil Questionnaire (describe):

Self-administered Internet Questionnaire (describe):

Other (describe):

Medical Record Abstraction (describe):

Biological Specimen Sample

Environmental Sample:

Other (describe):

7. Type of Information to be Collected: *Instruction: Select all that apply. For each type of information to be collected, provide a brief description. Use as much space as necessary for the description.*

Behaviors (describe):

e.g., handwashing, bathing, diapering, surface cleaning

Clinical information/symptoms (describe):

Date of onset, signs, symptoms, treatment, duration of illness, outcome

Contact information (describe):

Phone number

Demographic information (describe):

Age, sex, race, ethnicity, address for purposes of assessing exposure to factors related to water quality

Environmental factors (describe):

Water source, what the person uses water for (consumption, personal hygiene, etc)

Exposures (describe):

e.g., dietary, drinking and recreational water, social gatherings

Medical history (describe):

Co-morbidities (e.g., immunocompromised), medications

Risk factors (describe):

Child care attendee or staff, long term care facility resident or staff, ill contacts, live with children who are in diapers

Specimen/lab information (describe): Travel history (describe): Other (describe):

8. Duration of Data Collection (number of weeks):

Research Determination: *Instruction: Indicate the research determination decision. If the decision is research, provide the research determination letter and IRB approval, if required.*

 Research Not Research

CDC Investigation Lead: *Instruction: Indicate the name, title, and affiliation of the person who will serve as the CDC lead for this investigation.*

Name: Title: Affiliation:

CDC Sponsoring Program and Primary Contact Person: *Instruction: Indicate the sponsoring CIO/Division/Branch for this investigation. Indicate the name, title, and contact information of the CDC Primary Contact Person for this investigation. Indicate the preferred method of contact during the OMB approval process. Note, contact person or a designee must be available during the OMB approval process in case questions arise.*

CIO/Division/Branch: Name: Title:

Certification: *Please read the certification carefully. Type your name to validate that you are providing certification. Note: If you incorrectly certify, the collection will be returned as improperly submitted or it will be disapproved. Certification should be signed by the CDC Primary Contact Person for this Investigation.*

I, [insert name of CDC sponsoring program contact], certify the following to be true:

1. The collection is voluntary.
2. Respondents will not be personally identified in any published reports of the study.
3. Information gathered will be primarily used to inform effective prevention and control measures.

CDC Sponsoring Program Primary Contact
Name:

Date of Certification:

Requested Approval Date (mm/dd/yyyy): *Instruction: Indicate the date by which approval is needed.*

**E-mail the completed form to the Information Collection Request Liaison (ICRL) or EIS program
ICRL designee.**