

**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]*

Undetermined source of *Elizabethkingia meningoseptica* bloodstream infection among Wisconsin residents — Wisconsin, 2016

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).*

Elizabethkingia meningoseptica is a rare gram-negative bacillus that is intrinsically multidrug-resistant, resulting in high mortality rates (estimates range from 23 to 52%). Most *E. meningoseptica* infections occur in healthcare settings; however, community-acquired sepsis cases have also been rarely reported.

On January 5, 2016, the Centers for Disease Control and Prevention (CDC) was notified by the Wisconsin Division of Public Health (WIDPH) of a cluster of 6 cases of *Elizabethkingia meningoseptica* infections occurring in patients from 3 facilities. Following identification of the initial cluster, a statewide review identified 22 ill patients with *E. meningoseptica* isolated during January 1, 2014–February 5, 2016 since September 26, 2015. The number of infections is above

the baseline of 1–2 cases per year. Upon initial investigation, these 22 ill patients have had a variety of healthcare and community exposures and co-morbidities, and the source of their infection has not been identified. The four most recent illness onsets occurred during January 28, 2016 to February 4, 2016, suggesting that the outbreak is ongoing. Identifying the source of the infection is critical to prevent new infections.

WIDPH is requesting CDC assistance with the following:

- 1) Identify and describe cases and potential risk factors and sources of infection through patient interviews and review of medical records;
- 2) Environmental sampling to assist in identifying the source of the infection; and
- 3) Identify the source of the outbreak and implement appropriate prevention and control measures.

This GenIC requests approval for urgent data collection necessary for prevention and control of *Elizabethkingia meningoseptica* infection, including:

1. Case Investigation Form (Appendix 1)

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):

Through interviews, patients or their proxies will be asked about possible risk factors for infection and exposures in the community and in healthcare settings.

Healthcare staff (describe):

For incomplete medical records, information will be obtained from healthcare and laboratory staff.

Laboratory staff (describe):

For incomplete medical records, information will be obtained from healthcare and laboratory staff.

Patients (describe):

Through interviews, patients or their proxies will be asked about possible exposures in the community and in healthcare settings.

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.*

Cases will be identified by reviewing state Department of Health records for cases of *Elizabethkingia meningoseptica* reported to them since November 2015. The investigation team

will follow-up with all cases or their proxies (if the case has died or too ill to respond) to complete an interview. A proxy is identified as the person most familiar with the cases medical history and risk factors. The team also will abstract clinical and lab information from medical records for each patient.

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):

Potential risk factors for infection will be identified through patient interview and medical chart abstraction.

Cross-sectional Study (describe):

Cohort Study (describe):

Case-Control Study (describe):

Other (describe):

Other ancillary response efforts to provide data leading to outbreak control will also be carried out.

Environmental Assessment (describe):

Environmental samples at homes and health facilities will be collected by the investigation team. Environment sampling activities will be completed by CDC staff.

Laboratory Testing (describe):

Based on findings from the descriptive analysis, samples (e.g., water, medical products) will be collected and tested for the presence of *E. meningoseptica*. Laboratory testing activities will be completed by CDC staff.

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):

Patients or their proxies who consent to an interview with the investigation team will be asked about potential risk factors, clinical history, and exposures. These interviews will be conducted face-to-face or by telephone, based on the interviewee's preference.

Telephone Interview (describe):

Patients or their proxies who consent to an interview with the investigation team will be asked about potential risk factors and clinical history. These

interviews will be conducted face-to-face or by telephone, based on the interviewee's preference.

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

Self-administered Internet Questionnaire (describe):

Other (describe):

Medical Record Abstraction (describe):

Data will be abstracted from patient medical records by CDC staff.

Biological Specimen Sample

Environmental Sample:

Environmental samples at homes and health facilities will be collected by CDC staff.

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):

Community exposures, such as swimming and use of saunas

Clinical information/symptoms (describe):

Signs and symptoms, procedures performed, medications received, and outcomes.

Contact information (describe):

Contact information will be collected solely for the purposes of conducting patient or their proxies interviews and will not be transmitted to CDC.

Demographic information (describe):

Age, sex, race, and city/county of residence will be collected by medical record abstraction

Environmental factors (describe):

Environmental samples at homes and health facilities will be collected by the investigation team.

Exposures (describe):

Information about outpatient visits, locations in the community visited (e.g., gyms, spas, restaurants), and other potential exposures.

Medical history (describe):

Pre-existing conditions, dates and locations of healthcare encounters (inpatient and outpatient), medical procedures, medical devices.

Risk factors (describe):

See exposures, medical history, behaviors, and clinical information.

Specimen/lab information (describe):

Diagnostic test results listed in the medical record

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, Maroya Walters, 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.**

EEI Information Collection Request Liaison:

Danice Eaton, PhD, MPH
EIS Program Staff Epidemiologist
EWB/DSEPD/CDC
2400 Century Center, MS E-92
Office: 404.498.6389
Deaton@cdc.gov

For internal use. Do not complete.

Date/Time initial GenIC received
by ICRL

Date/Time final GenIC received
by ICRL

Date/Time submitted to OMB

Date/Time approved