

**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 risk factors of *Elizabethkingia anophelis* infections 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 anophelis is a rare, gram-negative bacillus identified in 2011 that is intrinsically multidrug-resistant, resulting in high mortality rates (estimates range from 23 to 52%). Although most *E. anophelis* infections have occurred in healthcare settings, community-acquired infections have also been reported.

On January 5, 2016, the Centers for Disease Control and Prevention (CDC) was notified by the Wisconsin Division of Public Health (WDPH) of an outbreak of *E. anophelis* infections. A joint CDC-WDPH investigation identified 66 cases of primarily community-associated infections, all occurring in southeastern Wisconsin, northeastern Illinois, or western Michigan, with specimen collection dates from November 23, 2015 to May 30, 2016. Patients have a variety of healthcare and community exposures and co-morbidities. Patient interviews were conducted with OMB Control #0920-1011 and Approved EEI-GenIC package 2016010-014. Hypothesis generating interviews, structured interviews, and environmental sampling did not identify a food, water

source, personal care product, healthcare product, or healthcare setting as a point source. The number of infections in the last quarter was 9 and above the baseline of 3-5. The last infection was reported to WDPH on June 6, 2016, corresponding to a culture collection date of May 30th, 2016.. Identifying a potential point source of infections is critical to prevent new infections and respond to a potential recrudescence of infections in Wisconsin. Focus group interviews with small subclusters of patients may identify a common, shared exposure missed by traditional outbreak investigation approaches.

WDPH is requesting CDC assistance with: 1) identification of potential exposures through patient focus groups and 2) apply findings from activity 1 to identify prevention and control measures.

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):
- Healthcare staff (describe):
- Laboratory staff (describe):
- Patients (describe):
- 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.*

Respondents will be selected based on molecular data, epidemiology, and ability and willingness to participate in a focus group discussion. Focus groups will be comprised of patients whose infections were genetically closely related or who shared an epi link, such as living in the same town.

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):

[Redacted]

Cross-sectional Study (describe):

[Redacted]

Cohort Study (describe):

[Redacted]

Case-Control Study (describe):

[Redacted]

Other (describe):

Qualitative investigation – focus group discussion

Environmental Assessment (describe):

[Redacted]

Laboratory Testing (describe):

[Redacted]

Other (describe):

[Redacted]

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):

[Redacted]

Telephone Interview (describe):

[Redacted]

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

[Redacted]

Self-administered Internet Questionnaire (describe):

[Redacted]

Other (describe):

[Redacted]

Medical Record Abstraction (describe):

[Redacted]

Biological Specimen Sample

[Redacted]

Environmental Sample:

[Redacted]

Other (describe):

Focus group discussion conducted face-to-face

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):

Activities that might have resulted in exposure to pathogen in environment – hunting,

fishing, gardening, hiking

 Clinical information/symptoms (describe): Contact information (describe): Demographic information (describe): Environmental factors (describe): Exposures (describe):

Food, water, personal care products

 Medical history (describe):

Medical encounters, including non-traditional care (e.g., acupuncture)

 Risk factors (describe): Specimen/lab information (describe): Travel history (describe):

Locations traveled to and activities during travel

 Other (describe):

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

2 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: Dr. Sharoda Dasgupta

Title: Epidemic Intelligence Service Officer

Affiliation: NCHHSTP

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: OID/NCEZID/DHQP/PRB

Name: Maroya Walters

Title: Epidemiologist

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