

**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). X Yes <input type="checkbox"/> No	The Investigation is initiated by CDC, without request from an external partner. <input type="checkbox"/> Yes X 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). X Yes <input type="checkbox"/> No	The investigation is not urgent in nature. <input type="checkbox"/> Yes X No
The investigation is characterized by undetermined agent, undetermined source, undetermined mode of transmission, or undetermined risk factors. X 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 X No
One or more CDC staff (including trainees and fellows) will be deployed to the field. X Yes <input type="checkbox"/> No	CDC staff (including trainees or fellows) are not deployed to the field. <input type="checkbox"/> Yes X No
Data collection will be completed in 90 days or less. X Yes <input type="checkbox"/> No	Data collection expected to require greater than 90 days. <input type="checkbox"/> Yes X 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 an outbreak of Legionnaires' Disease among Hotel A Visitors — Hannibal, MO 2015.

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).*

On June 29 2015, CDC detected within their travel surveillance system two initial laboratory-confirmed cases of legionellosis (onsets of illness March 7, 2015 and June 7, 2015). Questioning revealed that both individuals reported staying in Hotel A within their incubation period. Since then, an additional case of legionellosis has been reported. This individual also reported staying at Hotel A and had an onset of illness of October 12, 2015. The third patient died from his illness. At present, the source of this outbreak remains unknown. Upon the identification of two initial cases, an environmental assessment was completed without any sampling. With the third case, the whirlpool spa was disinfected and five environmental samples were collected. All environmental samples are negative to date. Autopsy of lung tissue from deceased case demonstrated *Legionella pneumophila*

serogroup 1 growth on culture. Sequence-based type testing is pending. Given heightened concern regarding the undetermined source of transmission and need for environmental capacity building within local and state health departments, the Missouri Department of Health requests CDC's assistance with an investigation to identify prevention and control measures.

The objectives are:

- 1) Assist in the environmental assessment of the risk of Legionnaires' disease at Hotel A
- 2) Develop and implement plans for additional environmental sampling and remediation to control the outbreak
- 3) Educate and train local and state epidemiologists and environmental public health staff on how to conduct environmental assessments and environmental sampling techniques for Legionnaires' disease control and prevention
- 4) Educate hotel staff and building management on epidemiology, disease transmission, and prevention.

The Epi-Aid will involve training and educating of local and health department staff on *Legionella* epidemiology, environmental assessment and environmental sampling techniques. Furthermore, face-to-face discussions with building management and maintenance regarding hotel hot water system design, whirlpool spa, swimming pool, and cooling tower maintenance. An environmental assessment survey instrument will be used by state and local health department staff to determine environmental risk factors within the hotel facility (Appendix 1). Once risk sites are identified, water sampling will be conducted and environmental samples will be recorded on data sample sheet (Appendix 2).

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):

Building Management, Maintenance staff

Healthcare staff (describe):

Laboratory staff (describe):

Patients (describe):

Restaurant staff (describe):

X Other (describe):

State and local health department officials

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.*

Local and State health departments involved in investigation and building management and maintenance staff at affected hotel.

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):

Other (describe):

X Environmental Assessment (describe):

- 1) Assist in the environmental assessment of the risk of Legionnaires' disease at Hotel A
- 2) Develop and implement plans for additional environmental sampling and remediation to control the outbreak

X Laboratory Testing (describe):

Environmental samples will be sent to CDC lab for identification of *Legionella* by culture or PCR.

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):

X Face-to-face Interview (describe):

We will speak to building management and maintenance staff regarding design of potable hot water system including cooling tower, whirlpool spa, and pool (Appendix 1).

Telephone Interview (describe):

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

Self-administered Internet Questionnaire (describe):

[Redacted]

Other (describe):

[Redacted]

Medical Record Abstraction (describe):

[Redacted]

Biological Specimen Sample

[Redacted]

Environmental Sample:

We will be utilizing environmental assessment tool to determine risk factors within the hotel for Legionella growth. We will also use a data sheet to record all samples collected from the hotel (Appendix 2).

Other (describe):

[Redacted]

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):

[Redacted]

Clinical information/symptoms (describe):

[Redacted]

Contact information (describe):

[Redacted]

Demographic information (describe):

[Redacted]

Environmental factors (describe):

We will be assessing the risk factors for Legionella growth within the building (Appendix 1).

Exposures (describe):

[Redacted]

Medical history (describe):

[Redacted]

Risk factors (describe):

[Redacted]

Specimen/lab information (describe):

[Redacted]

Travel history (describe):

[Redacted]

Other (describe):

[Redacted]

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

1 week

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:	Laura Cooley
Title:	Medical Epidemiologist
Affiliation:	CDC/NCIRD/DBD/RDB

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:	CDC/NCIRD/DBD/RDB
Name:	Laura Cooley
Title:	Medical 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, [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:	Laura Cooley
Date of Certification:	11/06/2015

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

11/07/2015

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