

**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

CLEARANCE 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 # 2014 - 004XXX

DATE 5/23/2014

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 and mode of transmission in a healthcare-associated Legionnaires' disease outbreak—Alabama, 2014

LOCATION OF INVESTIGATION: *Instruction: Indicate location where investigation will occur. If multiple locations, specify each one.*

State: Alabama

City/County (if applicable)

Country: USA

REQUESTING AGENCY: *Instruction: Indicate name of agency requesting epidemiological assistance and the name and position title of the requestor*

Agency: Alabama Department of Public Health

Name and Position Title: Dr. Mary G. McIntyre, M.D., M.P.H., SSBB, State Epidemiologist

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. At a minimum, please provide the following information: 1) background necessary to understand the importance of the outbreak or event; 2) justification of the need for an investigation, including a description of any data already available or data gaps that exist; 3) justification as to why this issue requires an urgent response; and 3) an explanation of how the information collected will be used to inform prevention and control measures. Use as much space as necessary (suggested length: 250-500 words).*

On May 20, 2014, the Alabama Department of Public Health notified CDC of 8 confirmed cases of Legionnaires' diseases among persons with Leukemia receiving inpatient care in Hospital A. Of the 8 case patients, 2 have died. The status of the remaining 6 case patients is being investigated, though we know at least 3 are still hospitalized and undergoing treatment. Additional, but undetected cases are possible among other inpatients and those with exposure to the hospital, such as visitors or hospital staff. The hospital conducted initial environmental sampling, which identified *Legionella* colonization in the potable water system. However, mode of transmission and risk factors for infection are not yet determined. Understanding why certain patients are infected and the mode of transmission are critical for identifying effective prevention and control measures.

In light of the 2 deaths and continued transmission risk to this vulnerable and high-risk immunocompromised population of leukemia patients, on May 22, 2014, the Alabama Department of Public Health requested CDC assistance to conduct an epidemiologic investigation to determine the extent of disease, and to identify, control, and mitigate any risks of continued exposure in Hospital A.

The objectives of this investigation are to:

1. Conduct an epidemiologic investigation to determine possible exposures and identify

additional cases of Legionnaires' disease among patients at University of Alabama, Birmingham.

2. Complete an environmental assessment of Legionnaires' disease risk and environmental sampling for Legionella at the hospital.
3. Recommend prevention and control measures to stop disease transmission and prevent additional morbidity and mortality.

Overview of investigation

The investigation will include the following components:

1. Case finding and case confirmation: Known cases of Legionnaires' disease will be reviewed and new cases of Legionnaires' disease associated with exposure to the hospital will be identified by reviewing hospital patient records and health department surveillance systems, laboratory records, and patient medical charts for symptoms and test results characteristic of Legionnaires' disease. A medical chart abstraction form will be used (Appendix 1). This form will be modified in the field based on data collection needs specific to this investigation. We anticipate abstracting records for approximately 15 patients; the burden is estimated at 15 minutes per medical record. Medical record abstraction might be completed by Alabama Department of Health staff and CDC.
2. Interviews of persons with suspected or confirmed Legionnaires' disease associated with Hospital A: Suspected or confirmed case patients or their family members (in the case of the deceased case patients) might be interviewed face-to-face or by telephone to identify risk factors for infection or characteristics associated with infection. Interviews will be conducted if sufficient information to determine risk factors for transmission and infection and to characterize the outbreak cannot be obtained through review of existing records (e.g., medical chart abstraction, laboratory records). If interviews are conducted, an interview questionnaire will be used (Appendix 2). This questionnaire will be modified in the field based on data collection needs specific to this investigation. We anticipate interviewing approximately 30 individuals; the burden per patient is estimated at 15 minutes.
3. Environmental investigation: An environmental assessment of the water system will be conducted, including additional environmental sampling of the water and swabs from the water fixtures.
4. Biospecimen samples: Urine samples from cases identified by the hospital might be collected and sent to CDC for confirmatory testing by urine Ag testing. Culture positive isolates from respiratory specimens may be sent to CDC for Sequence Based Typing which will help correlate with the environmental isolates. Biospecimen samples, if taken, might be collected by the Alabama Department of Health or Hospital A solely though CDC will assist if requested by the state to do so.

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):

Persons who visited the hospital during the outbreak period who develop healthcare-associated Legionnaires' disease or symptoms characteristic of Legionnaires' disease

Healthcare staff (describe):

Healthcare staff in Hospital A working in the proximity of case patients during the outbreak period who develop healthcare-associated Legionnaires' disease or symptoms characteristic of

Legionnaires' disease

Laboratory staff (describe):

Patients (describe):

Persons who were inpatients in Hospital A during the outbreak period and developed healthcare-associated Legionnaires' disease or symptoms characteristic of Legionnaires' disease

Restaurant staff (describe):

Other (Travelers on conveyances):

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 Hospital A patients, staff or visitors who develop healthcare-associated Legionnaires' disease or symptoms characteristic of Legionnaires' disease. These respondents will be identified through hospital diagnosis (ICD 9 codes, laboratory testing) and public health surveillance. Individuals with Legionnaires' disease or symptoms characteristic of Legionnaires' disease will be interviewed. We estimate the number to be 15 but it is possible that there may be more.

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):

This study will describe the occurrence and transmission of Legionnaires' disease among persons who have been exposed to Hospital A and who develop healthcare-associated Legionnaires' disease or symptoms characteristic of Legionnaires' disease.

Cross-sectional Study (describe):

Cohort Study (describe):

Case-Control Study (describe):

Other (describe):

Environmental Assessment (describe):

We will conduct environmental assessment of the water system and take additional water samples

Laboratory Testing (describe):

Urine Ag and respiratory isolates of positive Legionella cultures might be run if biological specimens are collected.

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):

This might be needed if the medical chart abstraction does not provide adequate information on risk factors for transmission. Interviews would be conducted with patients, hospital staff, or visitors with confirmed healthcare-associated Legionnaires' disease or symptoms consistent with Legionnaires' disease. Interviews would be conducted either face-to-face or by telephone, depending on the location and availability of the respondent, using an interview questionnaire (Attachment 2) that will be modified in the field based on the needs of this investigation.

Telephone Interview (All Contacts):

This might be needed if the medical chart abstraction does not provide adequate information on risk factors for transmission. Interviews would be conducted with patients, hospital staff, or visitors with confirmed healthcare-associated Legionnaires' disease or symptoms consistent with Legionnaires' disease. Interviews would be conducted either face-to-face or by telephone, depending on the location and availability of the respondent, using an interview questionnaire (Attachment 2) that will be modified in the field based on the needs of this investigation..

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

Self-administered Internet Questionnaire (describe):

Other (describe):

Medical Record Abstraction:

If persons admitted to a hospital have confirmed healthcare-associated Legionnaires' disease or symptoms consistent with Legionnaires' disease, clinical information will be abstracted from medical records using a medical chart abstraction form (Appendix 1) that will be modified in the field based on the needs of this investigation.

Biological Specimen Sample

Urine samples might be collected from patients diagnosed with Legionnaires's disease to confirm diagnoses.

Environmental Sample:

Samples will be taken from environment and water sources

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 (All patients and contacts):

Areas of Hospital A exposed to during hospital stay or visit

Clinical information/symptoms (All patients and contacts):

Symptoms consistent with Legionnaires' disease such as cough, fever, lower respiratory tract

symptoms, pneumonia

Contact information (Contacts of symptomatic contacts):

Demographic information (All contacts):

Age, gender, race and ethnicity, country of birth, country of residence

Environmental factors (describe):

Possible sites of exposure to water in Hospital A

Exposures :

Medical history (Symptomatic contacts):

Relevant past medical history particularly of immunosuppressive conditions or medications, co-morbid conditions

Risk factors (describe):

Exposure to possible water source in the hospital

Specimen/lab information (Symptomatic contacts):

Urine and respiratory secretions

Travel history:

Other (describe):

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

3 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

INVESTIGATION LEAD: *Instruction: Indicate the name, title, and affiliation of the person who will be leading the investigation.*

Name: Louise Francois Watkins

Title: EIS Officer

Affiliation: Respiratory Disease Branch, DVD/ Epidemiology Workforce Branch, DSEPD

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: NCIRD/ DBD

Name: Preeta K. Kutty

Title: Medical Epidemiologist

Contact Information: *Provide complete contact information. Check box for preferred method(s) of contact during the OMB approval process.*

<input checked="" type="checkbox"/> Office phone:	404-639-0470
<input type="checkbox"/> Home phone:	
<input checked="" type="checkbox"/> Cell/Mobile:	480-747-5409
<input checked="" type="checkbox"/> E-mail:	pkutty@cdc.gov
<input type="checkbox"/> Other:	

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), Danice Eaton.

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 received by ICRL	5/22/14; 7:04PM
Date/Time submitted to OMB	
Date/Time approved	

