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). ☒ Yes ☐ No	The Investigation is initiated by CDC, without request from an external partner. ☐ Yes ☒ 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). ☒ Yes ☐ No	The investigation is not urgent in nature. ☐ Yes ☒ No
The investigation is characterized by undetermined agent, undetermined source, undetermined mode of transmission, or undetermined risk factors. ☒ Yes ☐ No	The investigation is conducted for the primary purpose of program evaluation, surveillance, needs assessment, or research to contribute to generalizable knowledge. ☐ Yes ☒ No
One or more CDC staff (including trainees and fellows) will be deployed to the field. ☒ Yes ☐ No	CDC staff (including trainees or fellows) are not deployed to the field. ☐ Yes ☒ No
Data collection will be completed in 90 days or less. ☒ Yes ☐ No	Data collection expected to require greater than 90 days. ☐ Yes ☒ 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 - 019 **Date** 09-23-2014

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 source, mode of transmission, and risk factors for Pseudomonas aeruginosa infections and deaths among neonatal intensive care unit (NICU) patients — California, 2013-2014.

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

State:	California
City/County (if applicable)	
Country	United States

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

Agency:	California Department of Public Health
Name and Position Title:	Gilberto F. Chávez, M.D., M.P.H., 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 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).*

Pseudomonas spp. are a type of bacteria found in the environment, including in water sources. Serious *Pseudomonas* infections usually occur in hospitalized individuals or individuals with weakened immune systems. Invasive infections can lead to severe illness and death. On September 15, 2014, CDC was notified of ongoing positive *Pseudomonas aeruginosa* cultures among patients in a neonatal intensive care unit (NICU) beginning in September 2013. Two infants died in November 2013 with *P. aeruginosa* bloodstream infections at which time the state was notified. Environmental cultures from water faucets in the NICU identified *P. aeruginosa* isolates, but none of the strain types matched patient isolates. In response, the facility had the water system evaluated and performed remediation. No further cases were identified until June 2014 when a new case of respiratory colonization was identified. Cases of colonization and infection continued through August 2014. On September 18, 2014 the California Department of Public Health (CDPH) notified CDC of an

additional *P. aeruginosa* bacteremia and death in a NICU patient. The total number of cases of colonization and infection is 13, including 3 deaths.

Because of the scope of the outbreak, potential for ongoing cases in the NICU, and CDC's expertise in healthcare-associated infection prevention, CDPH is requesting CDC assistance with an urgent public health investigation.

The objectives and data collection plans are listed below:
1) Conduct case-finding and case confirmation
A search for additional cases will be conducted by reviewing microbiology records and medical records (Chart Abstraction Form, Appendix 1; this form might be modified in the field based on the needs of the investigation). Clinical characteristics of identified cases will be reviewed for case confirmation and to document potential risk factors.

2) Perform infection control assessment
The investigation team will conduct observations of infection prevention practices, such as central venous line insertion and maintenance practices, hand hygiene, and respiratory therapy. A draft of the hand hygiene observation form (Appendix 2) and the Central line-associated bloodstream infections (CLABSI) prevention checklist are included (Appendix 3). Interviews with infection prevention staff will be conducted (Appendix 4). These forms might be modified in the field based on the needs of the investigation.

3) Assess risk factors for colonization and infection in the NICU under investigation
A case-control study will be conducted to assess for risk factors for *P. aeruginosa* infection in the NICU under investigation. Risk factor and exposure information will be abstracted from medical records for cases and controls (Chart Abstraction Form, Appendix 1).

4) Perform environmental evaluation
A review of existing facility records of water testing will be conducted. Based on information collected during the investigation, water and other environmental samples might be collected and submitted to CDC for culture and molecular typing of isolates.

5) Make recommendations for control measures
Recommendations for infection prevention will be made on the basis of the investigation findings.

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

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

2. 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):
  Healthcare staff who are involved in providing care to the patients in the NICUs

☒ Laboratory staff (describe):
Clinical microbiology laboratory staff at the hospital

☒ Patients (describe):
Will abstract information from patient medical records

☐ Restaurant staff (describe):

☐ Other (describe):

3. 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.*

Medical records for all case-patients will be reviewed. Controls will be selected among patients admitted to the NICU during the same time period as the cases who have positive clinical or surveillance culture for *P. aeruginosa*. Interviews will be conducted with relevant healthcare facility staff, including infection prevention personnel, healthcare personnel providing direct patient care, facilities maintenance staff, and environmental services staff. An environmental evaluation focused on potential water sources will be conducted in NICU.

4. 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):
Characteristics of cases may be described. Patient care and water exposures may be described

☐ Cross-sectional Study (describe):

☐ Cohort Study (describe):

☒ Case-Control Study (describe):
A case-control study of cases and selected controls may be performed. Controls will be selected among patients treated in the NICU during the same time period as the cases.

☐ Other (describe):

☒ Environmental Assessment (describe):
Samples of water and environmental surfaces may be collected. Results of samples collected by a consulting firm hired by the hospital will be reviewed.

☒ Laboratory Testing (describe):
Cultures and molecular typing of isolates from environmental specimens or healthcare personnel hands may be performed

☐ Other (describe):

5. 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):

Interviews (Appendix 4) with facility staff will be conducted face-to-face or by telephone, depending on their location and availability.

☐ Telephone Interview (describe):

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

☐ Self-administered Internet Questionnaire (describe):

☒ Other (describe):

Direct Observation: The investigation team will conduct observations of infection prevention practices (e.g., hand hygiene and central line-care) to identify modes of transmission (Appendices 2 and 3).

☒ Medical Record Abstraction (describe):

Clinical and risk factor information will be abstracted from existing patient medical records using a chart abstraction form (Appendix 1) that will be modified in the field based on the needs of the investigation.

☐ Biological Specimen Sample

☒ Environmental Sample:

Samples may be taken from environmental sources (e.g., water, surface samples)

☒ Other (describe):

Samples may be taken from healthcare personnel hands

6. 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):

☒ Clinical information/symptoms (describe):

Timing of symptoms consistent with *Pseudomonas* infection relative to treatment, and clinical outcomes such as sepsis and death

☐ Contact information (describe):

☒ Demographic information (describe):

Age, race, gender

☐ Environmental factors (describe):

☐ Exposures (describe):

☒ Medical history (describe):

Relevant comorbidities such as immunosuppressive conditions, birth history

☒ Risk factors (describe):

Medications and oral and skin care products received, water exposures, devices in place, healthcare personnel exposure, room locations

☒ Specimen/lab information (describe):

Clinical samples will not be collected. However, if case-patient isolates are identified from specimens previously collected for surveillance or diagnostic purposes, these may be sent to CDC for further testing.

☐ Travel history (describe):

☐ Other (describe):

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

3-4 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:	Cara Bicking-Kinsey
Title:	EIS Officer
Affiliation:	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:	NCEZID/DHQP
Name:	Carolyn Gould
Title:	Team Lead/Medical Officer

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:	Carolyn Gould
Date of Certification:	9/23/2014

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

9/23/2014

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	9/11/2014; 5:32AM
Date/Time final GenIC received by ICRL	9/12/2014; 10:15AM
Date/Time submitted to OMB	9/12/2014; 10:30AM
Date/Time approved	9/15/2014; 12:52PM
