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 <u>can</u> be used. If you select "yes" to any criterion in Column B, the EEI Generic ICR mechanism <u>cannot</u> be used.*

Column A	Column B
CDC epidemiological assistance is requested by	The Investigation is initiated by CDC, without
one or more external partners (e.g., local, state,	request from an external partner.
tribal, military, port, other federal agency, or	Yes No
international health authority or other partner	
organization).	
Yes No	
The investigation is urgent in nature (i.e., timely	The investigation is not urgent in nature.
data are needed to inform rapid public health action	Yes No
to prevent or reduce injury, disease, or death).	<u> </u>
Yes No	
The investigation is characterized by undetermined	The investigation is conducted for the primary
agent, undetermined source, undetermined mode of	purpose of program evaluation, surveillance, needs
<u>transmission</u> , or undetermined risk factors.	assessment, or research to contribute to
Yes No	generalizable knowledge.
	Yes No
One or more CDC staff (including trainees and	CDC staff (including trainees or fellows) are not
fellows) will be deployed to the field.	deployed to the field.
Yes No	Yes No
Data collection will be completed in 90 days or	Data collection expected to require greater than 90
less.	days.
Yes No	Yes No

Did you select "Yes" to *all* criteria in Column A?

If yes, the EEI Generic ICR may be appropriate for your investigation. \rightarrow 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. \rightarrow Stop completing this form now.

GenIC#	2014	-	019	Date	09-23-2014
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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

	File Name: 2014019-078_Pseudomonas NICU_CA additional <i>P. aeruginosa</i> 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 <i>P. aeruginosa</i> 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

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

2. Respondents: Instruction: Select all that apply. For each respondent type selected, provide a brief

Date Form Revised: GenIC 6.16.14

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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: <i>Instruction: Provide a brief description of how respondents will be</i>			
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 <i>P. aeruginosa</i> . 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):			
Cahart Study (dagariba)			
Cohort Study (describe):			
Casa Control 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: <i>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.</i> Behaviors (describe):
Clinical information/symptoms (describe):
Timing of symptoms consistent with <i>Pseudomonas</i> 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

File Name: 2014019-078_Pseudomonas NICU_CA \times 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. Not Research Research **CDC Investigation Lead:** *Instruction: Indicate the name, title, and affiliation of the person who will* serve as the CDC lead for this investigation. Cara Bicking-Kinsey Name: Title: **EIS Officer** Epidemiology Workforce Branch, DSEPD 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. NCEZID/DHQP CIO/Division/Branch: Carolyn Gould Name: 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 9/23/2014 Date of Certification:

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

Date/Time final GenIC received by ICRL

Date/Time submitted to OMB

Date/Time approved

9/11/2014; 5:32AM

9/12/2014; 10:15AM

9/12/2014; 10:30AM

9/15/2014; 12:52PM