

**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.*

<b>Column A</b>	<b>Column B</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]*

**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).*

custody is turned over to HHS/Administration for Families and Children (ACF)/Office of Refugee Resettlement (ORR) for placement in shelters or facilities operated and managed by ACF/ORR until reunification with parents or family located within the U.S. or other arrangements are made. While location of individual shelters is sensitive information; shelters tend to be located in large states with large immigrant populations, such as California, Texas, Oklahoma, and New York. Approximately 4,000 children are currently being sheltered and cared for at these US Government (USG) facilities.

Because of the large numbers of unaccompanied children arriving in a short period of time, these Customs and Border Protection holding facilities and ORR shelters (i.e., USG UAC shelters) are crowded, impacting public health conditions within the facilities and increasing the likelihood for the occurrence and spread of infectious diseases, including respiratory illnesses. As of July 13, confirmed and suspect respiratory illness clusters have been reported in multiple shelters.

On July 11, CDC was notified of a respiratory illness cluster at the Ventura Naval Base temporary shelter, where 5 children had been hospitalized in Ventura County. While both pneumonia and influenza were confirmed, the primary agent, source, and risk factors in this outbreak are undetermined. In response, an Emergency Epidemic Investigation GenIC was submitted on July 12 and approved by OMB on July 13 to assist ORR with an investigation to determine the agent, source, and risk factors for infection in this respiratory illness cluster.

After the initial GenIC for the investigation in Ventura, CA was submitted to OMB, additional respiratory clusters have been confirmed at two additional Unaccompanied Alien Children's shelters in Texas and Arizona. Late in the evening of July 12, 2014, ORR informed CDC about additional cases of respiratory illness in an ORR permanent shelter in Texas. All cases are in males aged between 14 and 17 years and were roommates at the shelter; 2 were determined to have pneumococcal bacteremia. They traveled on the same bus to the shelter from the Rio Grande Valley region, but did not come via the Nogales processing center and have no known epidemiologic links to the Ventura cases. At the same time, a respiratory illness cluster was reported at a Texas facility. Additional respiratory illness clusters are suspected at other USG UAC shelters. An urgent investigation is needed to determine the scope of the outbreak, identify any potential sources of infection early during the processing of these children, identify predisposing factors and other risk factors for these respiratory illnesses, to determine the primary agent of the outbreak, identify contacts of ill children, and to implement appropriate measures to control and limit respiratory illnesses in this vulnerable population.

Because these shelters house a common population and operate under a single authority (USG), processing and transfer of UAC across multiple USG shelters is possible. In addition, similar environmental conditions are present across shelters. As such, ORR requests assistance with an investigation of currently known and newly identified respiratory illness clusters in USG UAC Shelters. Thus, CDC is submitting this new Emergency Epidemic Investigations GenIC request to obtain approval to assist ORR in investigating illness outbreaks in USG UAC shelters.

A descriptive study will be conducted to identify the primary agent and source of the outbreak. Traceback contact tracing will be done to identify risk factors for exposure. Ill case patients will be interviewed to identify potential contacts and risk factors. A template case investigation form is provided in Appendix 1 and will be tailored for this investigation and modified as necessary in the field. Blood specimens will be sent for serotyping of pneumococcal isolates to determine if respiratory illness clusters involve a single strain or multiple strains. Medical records will be reviewed to confirm case status and identify underlying conditions; a template medical record form is provided in Appendix 2 and will be tailored for this investigation and modified as necessary in the field. An environmental assessment of shelters will be conducted to identify potential sources and risk factors for infection. CDC will assist ORR and local health authorities with collection of blood specimens as requested following local policies and procedures for collection, storage, transport, and

testing of specimen. Either randomized or systematic samples will be taken from healthy persons in shelters to determine the extent of spread within the shelter population and determine rate of asymptomatic illness. Specimens from all ill persons or those potentially exposed will be sent for both bacterial and viral testing at state public health laboratories and at CDC as appropriate. Additional investigation components might be added, or modifications to those described here might occur, including investigation of other potential urgent health issues, based on information that is obtained in the field.

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):  

Ill or potentially exposed unaccompanied alien children in USG UAC shelters
- Healthcare staff (describe):
- Laboratory staff (describe):
- Patients (describe):  

Hospitalized unaccompanied alien children
- 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 are ill or potentially exposed unaccompanied alien children (UAC) in temporary shelters. UAC are under the legal custody and care of ORR. Ill children are those whose medical appointees and the public health department have identified as ill.

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):  

A descriptive study will be conducted to identify the primary agent and source of the outbreak. Trace back contact tracing will be done to identify risk factors for exposure and, due to movement between facilities, likely will include multiple USG UAC shelters.
  - Cross-sectional Study (describe):

[Redacted]

Cohort Study (describe):  
[Redacted]

Case-Control Study (describe):  
[Redacted]

Other (describe):  
[Redacted]

Environmental Assessment (describe):  
[Redacted]

Laboratory Testing (describe):  
Serotyping of pneumococcal isolates to determine if the cluster involves a single strain or multiple strains. CDC will assist ORR and local health authorities with collection of blood specimens as requested following local policies and procedures for collection, storage, transport, and testing of specimen.

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):  
Face-to-face interviews will be conducted with ill case patients to identify contacts and interactions with ill persons in cluster (template case investigation form, Appendix 1).

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):  
Review medical records of hospitalized UAC (template medical record form, Appendix 2)

Biological Specimen Sample  
Blood for serology will be collected, or obtained from existing samples already taken by hospital. CDC will assist ORR and local health authorities with collection of blood specimens as requested following local policies and procedures for collection, storage, transport, and testing of specimen.

Environmental Sample:  
[Redacted]

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):

Clinical information/symptoms (describe):

Such as respiratory symptoms, fever, diagnoses

Contact information (describe):

Interaction with other ill persons

Demographic information (describe):

Environmental factors (describe):

Shelter size and capacity. Shelter facilities, handwashing, etc.

Exposures (describe):

Contact with ill persons

Medical history (describe):

Vaccination history if available, predisposing health conditions if known

Risk factors (describe):

Contact with ill persons

Specimen/lab information (describe):

Blood for serology

Travel history (describe):

Modes of transport, travel companions, duration of travel, previous USG shelters

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: Steve Waterman

Title: Lead, US-Mexico Unit

Affiliation: Division of Global Migration and Quarantine, NCEZID

**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:

Name:

Title:

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**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, [Clive M Brown], 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

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For internal use. Do not complete.

Date/Time initial GenIC received by ICRL	7/13/2014, 2:00PM
Date/Time final GenIC received by ICRL	7/14/2014,
Date/Time submitted to OMB	
Date/Time approved	

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