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 # 2014012 - XXX **Date** 07/12/2014

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 agent and risk factors in a cluster of respiratory illnesses among unaccompanied alien children housed at a temporary shelter—California, 2014

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

State: California

City/County (if applicable) Ventura County

Country USA

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

Agency: Office of Refugee Resettlement, HHS

Name and Position Title: Curi Kim, Director, Division of Refugee Health

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).*

There has been a surge of Unaccompanied Alien Children (UAC) entering the United States by way of its southern border. Between January and June of 2014, approximately 50,000 minors have been found along the southern border, nearly the total number of children identified in 2013 (40,000), and twice the number apprehended at this point last year (17,500). The top four countries of origin were Honduras, El Salvador, Mexico, and Guatemala. The majority of unaccompanied children are concentrated in the Rio Grande Valley (RGV) Sector of Texas. Following initial screening, the majority of these children are being processed through the Nogales Processing Center in Arizona. Once UACs are processed by CBP, 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. Currently, the temporary shelter in use are located at Lackland air force base (AFB), Sill AFB, and Ventura AFB. Approximately 4,000 children are currently being sheltered and cared for at US Government (USG) facilities. Because of the large numbers of unaccompanied children arriving in a short period of time, Customs and Border Protection holding facilities and ORR shelters are crowded, impacting public health conditions within the facilities and increasing the likelihood for the occurrence and spread or respiratory illnesses.

On July 11, 2014, CDC was informed by the California Department of Public Health (CDPH), Ventura County DPH, and ORR about 5 children (4 males), aged between 14 and 16 years, from Ventura AFB temporary shelter hospitalized in Ventura County hospitals starting July 6. All were previously transferred from Nogales (dates not known); 3 males are in ICU; 2 males haves lobar pneumonia, one has pneumococcal bacteremia; 2 males have influenza, one with influenza B also has pneumococcal bacteremia, the other is due to H1N1. It is not known if the primary agent in the outbreak is influenza with superimposed pneumococcal infection or if it is pneumococcal infection with superimposed influenza infection. Two were known to be housed in the same room but there is little or no information about circumstances and risk factors in these fatalities making it difficult to make appropriate disease intervention and control decisions.

An urgent investigation is needed to determine the scope of the outbreak, identify predisposing factors and other risk factors for these respiratory illnesses, to determine the primary agent of the outbreak, and to implement appropriate measures to control and limit respiratory illnesses in this vulnerable population.

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. Ill case patients will be interviewed to identify potential contacts and risk factors. An example interview form is provided in Appendix 1; this form 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 the cluster involves a single strain or multiple strains. Medical records will be reviewed to confirm case status and identify underlying conditions. An environmental assessment of the shelter will be conducted to identify potential sources and risk factors for infection. CDC will assist ORR and CDPH 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. Swabs from all ill persons will be sent for both bacterial/viral testing at CDPH public health laboratory and at CDC as appropriate. Additional investigation components might be added, or modifications to those described here might occur, based on new 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 temprorary 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.

☐ Cross-sectional Study (describe):

☐ Cohort Study (describe):

☐ Case-Control Study (describe):

☐ Other (describe):

☐ Environmental Assessment (describe):

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

☐ 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):

Face-to-face interviews will be conducted with ill case patients to identify contacts and interactions with ill persons in cluster (example interview form, Attachment 1).

☐ Telephone Interview (describe):

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

☐ Self-administered Internet Questionnaire (describe):

☐ Other (describe):

☒ Medical Record Abstraction (describe):

Review medical records of hospitalized UAC

☒ Biological Specimen Sample

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

☐ Environmental Sample:

☐ 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 (describe):

☒ Clinical information/symptoms (describe):

☒ 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):

Contract with ill persons

☒ Specimen/lab information (describe):
Blood for serology

☒ Travel history (describe):
Modes of transport, travel companions, duration of travel

☐ 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: NCEZID/DGMQ/USMU

Name: Steve Waterman

Title: Lead, US-Mexico Unit/DGMQ/NCEZID

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: Clive M Brown

Date of Certification: 1/24/217/12/2014

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

1/24/217/13/2014

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	7/11/2014, 11:29PM
Date/Time final GenIC received by ICRL	7/12/2014, 11:10AM
Date/Time submitted to OMB	
Date/Time approved	
