**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).<br>☒ Yes ☐ No | The Investigation is initiated by CDC, without request from an external partner.<br>☐ 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).<br>☒ Yes ☐ No | The investigation is not urgent in nature.<br>☐ Yes ☒ No |
| The investigation is characterized by undetermined agent, undetermined source, undetermined mode of transmission, or undetermined risk factors.<br>☒ Yes ☐ No | The investigation is conducted for the primary purpose of program evaluation, surveillance, needs assessment, or research to contribute to generalizable knowledge.<br>☐ Yes ☒ No |
| One or more CDC staff (including trainees and fellows) will be deployed to the field.<br>☒ Yes ☐ No | CDC staff (including trainees or fellows) are not deployed to the field.<br>☐ Yes ☒ No |
| Data collection will be completed in 90 days or less.<br>☒ Yes ☐ No | Data collection expected to require greater than 90 days.<br>☐ 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 #** 20140018 - XXX **Date** 09/19/2014

**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 etiology, mode of transmission, and risk factors for pediatric cluster of neurologic symptoms following respiratory illness, Colorado, 2014

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

| | |
|---|---|
| State: | Colorado |
| City/County (if applicable) | Denver |
| Country | USA |

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

| | |
|---|---|
| Agency: | Colorado Department of Public Health and Environment (CDPHE) |
| Name and Position Title: | **Lisa Miller MD, MSPH**, 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).*

On September 16, 2014, CDC was notified by Colorado Department of Public Health and Environment (CDPHE) of nine cases of acute central nervous system disease among pediatric patients. The cases were identified during August 4–September 17, 2014 among children aged 1–18 years (median age 9 years), most from the greater Denver metropolitan area. The patients suffered acute neurologic symptoms including cranial nerve palsies, weakness in one or more limbs, headache, and photophobia and all were hospitalized. Some patients reported a febrile respiratory illness during the 2 weeks preceding development of neurologic symptoms. Cerebrospinal fluid (CSF) analysis has demonstrated increased white blood cell count (pleocytosis). Magnetic resonance imaging (MRI) for all patients have shown significant demyelinating lesions in the spinal

cord, brain, and/or cranial nerves. Six patients have tested positive for rhinovirus/enterovirus via respiratory virus panels. Two of the six cases have tested positive for EV-D68 through confirmatory testing at CDC's Picornavirus Laboratory.

All cases have been reported from one hospital. Some of the presenting cases have required treatment in an intensive care unit; current number of hospitalized cases is unknown. This hospital has indicated that this is an unusual number of cases of these neurological symptoms. Data collection will focus on this facility, however if more cases are identified in other facilities, data collection may extend to new areas.

The Colorado Department of Public Health and Environment requests CDC assistance with an investigation to assist the state and local health department with the investigation to better characterize the common clinical presentation among reported patients consistent with neurological syndromes being currently investigated.

Objectives of this mission are:

1. Assist the state and local health department with the investigation including to better characterize the common clinical presentation among reported patients consistent with neurologic syndromes being currently investigated.
2. Characterize the epidemiology of the acute neurologic syndrome cases.
3. Evaluate potential non-infectious and infectious etiologies including through laboratory testing for enteric respiratory and zoonotic pathogens (including circulating viruses enterovirus-D68, West Nile Virus, and other possible pathogens).
4. Develop a standard approach within this outbreak, to investigate cases of acute myelitis/AFP in order to apply to other cases as they are reported, as requested by the Colorado department of health in their health alert.

Currently, two data collection tools have been created to collect information about case-patients. These include a medical chart abstraction form (Appendix 1) and an interview questionnaire (Appendix 2) for the primary care-giver of case-patients. Interviews will be conducted in-person or on the telephone, depending on their location. These forms might be modified or additional data collection instruments created in the field based on the needs of the investigation.

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):

The primary care-giver of case-patients will be interviewed using a standardized questionnaire to understand exposures that could be associated with illness.

☒ Healthcare staff (describe):

Staff providing care for the case-patients might be interviewed and medical records abstracted using standardized form to identify symptoms signs and imaging pathology.

☐ Laboratory staff (describe):

NA

☒ Patients (describe):

Chart abstraction will be used to collect diagnoses, symptoms, signs, imaging results and treatment information about case-patients.

☐ Restaurant staff (describe):

NA

☒ Other (describe):

In an effort to identify baseline rates to determine if the cluster represents an increase in expected rates, a review of imaging and records from corresponding period in previous years may be conducted.

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.*

Families of case-patients and hospital staff who provided care will be identified using hospital records. Telephone or in-person interviews will be conducted with primary caregivers of confirmed or suspected case-patients.

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 is a descriptive study to systematically collect information about clinical illness and potential exposures associated with neurologic illness in order to identify risk factors and modes of transmission.

☐ Cross-sectional Study (describe):

☐ Cohort Study (describe):

☐ Case-Control Study (describe):

☐ Other (describe):

☐ Environmental Assessment (describe):

☐ Laboratory Testing (describe):

☐ 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):
Families of case-patients might be interviewed in-person depending on their location (Appendix 2).

☒ Telephone Interview (describe):
Families of case-patients will be contacted by telephone for interview. (Appendix 2)

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

☐ Self-administered Internet Questionnaire (describe):

☐ Other (describe):

☒ Medical Record Abstraction (describe):
Medical records of case-patients will be identified for abstraction of key clinical information (Appendix 1)

☐ Biological Specimen Sample

☐ 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):
Attendance at daycare, doctors' offices, hospitals.

☒ Clinical information/symptoms (describe):
Clinical symptoms compatible with myelitis or flaccid paralysis, among cases and potential contacts.

☒ Contact information (describe):
Telephone number, email, residence address.

☒ Demographic information (describe):
Name, Sex, DOB, Race, ethnicity.

☐ Environmental factors (describe):

☒ Exposures (describe):
Information regarding exposures to potentially infected people will be collected.

☒ Medical history (describe):
Past medical history and medication history of case-patients will be collected.

☒ Risk factors (describe):
Risk factors for this illness are currently unknown. The questions are broad in order to formulate hypotheses regarding risk factors and routes of transmission.

☒ Specimen/lab information (describe):
We are not collecting specimens. We will review laboratory data from the medical chart.

☐ Travel history (describe):

☒ Other (describe):
Neuroimaging records, a component of the medical chart.

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: | Dr. Daniel Pastula and Dr. Negar Aliabadi |
| Title: | Epidemic Intelligence Officers |
| Affiliation: | CDC- Arboviral Diseases Branch and NCIRD/DVD/EB |

**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.*

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|---|---|
| CIO/Division/Branch: | NCIRD/DVD/EB |
| Name: | Susan Gerber, MD |
| Title: | Medical Officer, NCIRD/DVD/EB |

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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, [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.

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|---|---|
| CDC Sponsoring Program Primary Contact Name: | Susan Gerber, MD |
| Date of Certification: | 09/19/14 |

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

9/19/14

**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.

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|---|---|
| Date/Time initial GenIC received by ICRL | 8/11/2014, 12:45 PM |
| Date/Time final GenIC received by ICRL | 8/12/2014, 10:28 AM |
| Date/Time submitted to OMB | 8/12/2014, 11:28 AM |
| Date/Time approved | 8/13/2014, 11:30 AM |

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