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 # 2019004 - XXX **Date** 8/28/2019

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]*

E-cigarette associated pulmonary illness

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

State:	Possible cases have been identified in the following states: CA, CO, CT, FL, GA, IA, IN, KS, MD, MI, MN, NC, NJ, NM, NY, OH, PA, TN, TX, UT, VA; over the course of the response we anticipate cases will be identified in an additional 10 states. States will be included in the data collection effort at their request.
City/County (if applicable)	
Country	USA

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

Agency:	Wisconsin Department of Health
Name and Position Title:	Jon Meiman, Chief Medical Officer, WI DOH

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).*

Introduction

211 possible cases of severe pulmonary disease associated with e-cigarette use were reported in 24 states from June 28, 2019 to August 26, 2019, including 1 case-patient death. No etiology has been identified. All case-patients report a history of e-cigarette use. Some case-patients report a history of vaping liquids containing tetrahydrocannabinol (THC) compounds.

On August 14 and August 16 the Wisconsin and Illinois Departments of Health, respectively, requested assistance from the Centers for Disease Control and Prevention (CDC) to assist with the investigation of the cases of illness in their states. Since that time, other state and local jurisdictions

have requested that CDC facilitate the investigation by aggregating case-patient information at the national level. A multi-state centrally coordinated investigation to severe pulmonary disease associated with e-cigarette use will assist each state/local/territory jurisdiction in making rapid, practical decisions for actions to prevent and control the public health problem. This approach will streamline and strengthen the response, as opposed to multiple state and jurisdictional investigations for the same public health issue.

With technical assistance from CDC, states have worked collaboratively to develop a standardized case definition (Appendix 1), medical chart abstraction short form (Appendix 2), and case interview short form (Appendix 3).

What is Known
Most case-patients reported a gradual onset of difficulty breathing, shortness of breath, or chest pain prior to hospitalization. Several consulted with primary care clinicians and were diagnosed with minor acute respiratory infections before presenting in emergency departments days later after their symptoms worsened. Upon workup, case-patients have no clinical indications of infection and have not improved with antibiotic therapies; several have experienced rapid improvement with steroid therapies.

What is Not Known
No etiology has been identified. While case-patients appear to be similar across states, it is unclear if these cases have resulted from a common disease process or different disease processes with similar manifestations.

The Role of CDC
The National Center for Injury Prevention and Control (NCIPC), National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), National Center for Environmental Health (NCEH), and National Institute for Occupational Safety and Health (NIOSH) are working together to provide technical assistance, coordination, and communication between states investigating these cases.

Data Collection Objectives
Assist the state and local health departments with

- Establishing criteria for identifying cases
- Better characterize potential exposures and evaluate potential non-infectious etiologies
- Investigating clinical signs/symptoms, radiographic results, and clinical treatments in cases.

This GenIC requests OMB approval for the medical chart abstraction short form (Appendix 2) and the case interview short form (Appendix 3) which will be distributed to states who wish to voluntarily use them to collect standardized data. The tool and questionnaire are based on instruments developed by the states to support their own investigations. If requested by the state, CDC will provide staff to assist with data collection within their jurisdiction. As part of public health response within each state, states may choose to collect identifying information for their own purposes, but this will not be at the request of CDC. Data will include potentially sensitive information (e.g., drug use) since preliminary information indicates some case patients were exposed to product containing THC.

CDC is currently working on a plan to leverage an existing secure data platform, such as RedCap or SEDRIC (CDC's System for Enteric Disease Response, Investigation, and Coordination), so that states will be able to securely transmit data to CDC. At the request of states, participating states will voluntarily share de-identified data with CDC via the secure data platform; shared data will include key variables that are most critical for understanding the distribution and characteristics of cases nationally and for identifying risk factors across states. CDC will aggregate key variable data to better understand the distribution and characteristics of cases nationally and identify shared risk

factors across states.

Although 206 cases have been reported to date, this GenIC estimates a burden of 500 cases since new possible cases and states with possible cases continue to be identified.

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

- [x] Undetermined agent
- [x] Undetermined source
- [ ] Undetermined mode of transmission
- [x] 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):
- [ ] Healthcare staff (describe):
- [ ] Laboratory staff (describe):
- [x] Patients (describe):
  Patients or their proxy for patients too ill to respond with e-cigarette associated pulmonary lung illness (Appendix 3)
- [ ] Restaurant staff (describe):
- [x] Other (describe):
  Health department staff who abstract medical charts (Appendix 2)

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.*

As part of on-going state-based surveillance, providers who identify a case with e-cigarette associated acute pulmonary disease report that case to the state health department.

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.*

- [x] Epidemiologic Study (indicate which type(s) below)
  - [x] Descriptive Study (describe):
    This is a descriptive study of patients with confirmed e-cigarette associated acute pulmonary disease to systematically collect information about potential exposures to e-cigarettes and specific substances (Appendices 2 and 3), e-cigarette associated behaviors (Appendix 3), and healthcare data related to acute presentations of illness (Appendices 2 and 3).
  - [ ] 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):

State health department staff will conduct telephone-based or in-person interviews of case-patients using a standardized case interview form (Appendix 3)

☒ Telephone Interview (describe):

State health department staff will conduct telephone-based or in-person interviews of case-patients using a standardized case interview form (Appendix 3)

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

☐ Self-administered Internet Questionnaire (describe):

☐ Other (describe):

☒ Medical Record Abstraction (describe):

State health department staff will collect medical records and conduct medical chart abstraction (Appendix 2).

☐ 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):
Appendices 2 and 3: Substance use behaviors. E-cigarette behaviors. Appendix 3: Occupation.

☒ Clinical information/symptoms (describe):
Appendices 2 and 3: Presenting symptoms. Appendix 2: Lab findings. Radiographic findings. Pathology findings

☐ Contact information (describe):

☒ Demographic information (describe):
Appendices 2 and 3: Age, sex, race, ethnicity

☐ Environmental factors (describe):

☒ Exposures (describe):
Appendices 2 and 3: Types of substances used

☒ Medical history (describe):
Appendix 2: Past medical history. Appendices 2 and 3: Medications. Substance use history

☒ Risk factors (describe):
Risk factors for this cluster remain unknown. The questions are broad in order to formulate hypotheses regarding risk factors. We will ask about relevant clinical history, substance use behaviors, e-cigarette behaviors (Appendices 2 and 3).

☐ Specimen/lab information (describe):

☐ Travel history (describe):

☐ Other (describe):

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

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:	Joshua Schier
Title:	Medical Officer
Affiliation:	NCIPC / DUIP / OD

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:	NCIPC / DUIP / OD
Name:	Erin Parker
Title:	Deputy Associate Director for Science, Division of Unintentional Injury Prevention

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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.

CDC Sponsoring Program Primary Contact Name:	Erin Parker
Date of Certification:	08/27/2019

Requested Approval Date (mm/dd/yyyy): *Instruction: Indicate the date by which approval is needed.*
08/29/2019

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
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