

**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]*

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.

**New Information:** Cases have been identified in 49 states (all except Alaska), the District of Columbia, and 2 U.S. territories (the United States Virgin Islands and Puerto Rico).

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:

Council of State and Territorial Epidemiologists

Name and Position Title:

Jeffrey P. Engel, Executive Director

*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).*

### Information from Original GenIC approved on 8/29/2019

#### 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, medical chart abstraction short form, and case interview short form.

### **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.

The GenIC approved on 8/29/2019 requested OMB approval for the medical chart abstraction short form (Attachment A) and the case interview short form (Attachment B) which was 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 had been reported to date, the GenIC approved on 8/29/2019 estimated a burden of 500 cases since new possible cases and states with possible cases continue to be identified.

**New Information for this GenIC Request:**

Data collections for this investigation were initiated following OMB approval on 8/29/2019 under the Emergency Epidemic Investigations (EEI) Generic ICR (OMB # 0920-1011, exp 1/31/2020). Per the terms of the EEI Generic ICR, data collection is approved for 90 days and therefore the currently approved EEI GenIC expires on 11/27/2019. To date (as of 11/20/19), data were collected from 2,290 people who have been reported to the CDC as a probable or confirmed case of severe pulmonary disease associated with e-cigarette use (now called E-Cigarette or Vaping Associated Lung Injury or EVALI). Data collection has not been completed within the original 90 days because new cases are still being reported to CDC from states and territories. Data from state health departments is currently being submitted securely to CDC using that Data Collation and Integration for Public Health Event Response (DCIPHER) platform.

On 11/8/2019, CDC reported results from 29 EVALI patient who underwent bronchoalveolar lavage (BAL) and found that all 29 samples contained vitamin E acetate and 23 of 26 samples contained THC ingredients. While it appears that vitamin E acetate is associated with EVALI, evidence is not yet sufficient to rule out contribution of other chemicals of concern to EVALI. Many different substances and product sources are still under investigation, and it may be that there is more than one cause of this outbreak.

This GenIC requests OMB approval to continue to collect data from patients with probable or confirmed cases of EVALI.

Since the start of the outbreak, we have been able to streamline the chart abstraction (Attachment A) and interview forms (Attachment B) included in the initial EEI GenIC approved by OMB by identifying the most essential information needed for the investigation to identify cases and associated risk factors for illness. These two forms are now replaced by a single National Case Report Form (National Case Report Form – Standard Version, Appendix 1).

**The National Case Report Form – Standard Version** is completed by clinicians or healthcare department staff through medical record abstraction of EVALI cases and includes demographic information, detailed information on past substance use, symptoms, laboratory and radiology findings, hospitalization, interventions, and diagnostic tests performed. The burden for this form is one hour. This form provides the detailed information necessary to inform our understanding of risk factors and clinical course of disease.

In lieu of the National Case Report Form – Standard Version, clinicians or healthcare staff may choose to complete a shorter form (**National Case Report Form – Abbreviated Version**). For respondents who are not able to complete the longer form, this shorter form provides the minimum information necessary to track case counts. This form is also completed by medical record abstraction and includes demographic information and less detailed information about vaping or e-cigarette use

and clinical information. The burden for this form is 30 minutes.

We anticipate an additional 1500 new cases over the next 90 days. Based on the details provided in case reports currently being received by CDC, for new cases reported over the next 90 days, we expect that clinicians or health department staff will submit the National Case Report Form – Standard Version (Appendix 1) for half of the cases (750) and the National Case Report Form – Abbreviated Version (Appendix 2) for half of the cases (750). We expect that approximately half of the states will opt to use the shorter form because many states report having less staff time available for data collection as the investigations has progressed.

To supplement information collected through the national case report forms, we describe below one additional data collection.

Upon request from states, CDC is accepting bronchoalveolar lavage (BAL) samples, blood and urine samples for analysis from confirmed EVALI cases. To submit these samples to CDC, public health laboratory staff of health departments complete the **Specimen Manifest Form (Appendix 3)** with information about the sample. This form takes approximately 10 minutes per specimen submitted to complete. CDC already has received 48 specimens using this form and anticipates receiving an additional 100 specimens.

Here is a summary of the burden requested and used **during the first 90 days** of data collection:

Medical Chart Abstraction Form - # respondents requested: 500

Medical Chart Abstraction Form - # actual respondents: 2108

Case Interview Short Form - # respondents requested: 500

Case Interview Short Form - # actual respondents: 1810

Specimen Manifest Form - # respondents requested: 0

Specimen Manifest Form - # actual respondents: 48

This GenIC requests approval for:

Appendix 1: National Case Report Form – Standard Version (750 respondents)

Appendix 2: National Case Report Form – Abbreviated Version (750 respondents)

Appendix 3: Specimen Manifest Form (100 specimens submitted by 20 respondents)

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):

Healthcare staff (describe):

Clinicians who abstract medical charts (Appendix 1 or Appendix 2)

Laboratory staff (describe):

Public health laboratory staff of local, state, territorial or tribal health departments who send samples to CDC will fill out a spreadsheet that identifies the type of sample (e.g., urine, whole blood) and other pertinent information such as volume of sample and collection date. (Appendix 3)

Patients (describe):

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.*

As part of on-going state-based surveillance, clinicians who identify a case with e-cigarette associated acute pulmonary disease report that case to the state health department and either the clinician or a health department staff person will complete the case report form. (Appendix 1 and Appendix 2). Public health laboratory staff who receive clinical specimens that are sent to CDC for testing complete the Specimen Manifest Form (Appendix 3).

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 of patients with confirmed e-cigarette associated acute pulmonary disease. Data are collected to determine confirmed and probably EVALI case counts (Appendix 1 and 2) and to describe the clinical progression of disease and determine potential risk factors (Appendix 2).

Cross-sectional Study (describe):

Cohort Study (describe):

Case-Control Study (describe):

Other (describe):

Environmental Assessment (describe):

Laboratory Testing (describe):

Human samples (blood, urine, BAL) collected from confirmed and probable EVALI cases during the course of receiving care in a medical setting will be sent to CDC for analysis. Samples will be collected by public health laboratory staff under the discretion of the clinical team treating individual patients. Public health laboratory staff who wish to submit the specimens for additional testing can send them to CDC (Manifest Form, Appendix 3). Samples received by CDC will be analyzed for analytes related to e-cigarette use and lung injury.

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):

Telephone Interview (describe):

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

Self-administered Internet Questionnaire (describe):

Other (describe):

Medical Record Abstraction (describe):

State health department staff or clinicians will collect medical records and conduct medical chart abstraction (Appendix 1 and Appendix 2).

Biological Specimen Sample

Human samples (blood, urine, BAL) collected from confirmed and probable cases during the course of receiving care in a medical setting will be sent to CDC for analysis. Samples will be collected by public health laboratory staff under the discretion of the clinical team treating individual patients. Public health laboratory staff who wish to submit the specimens for additional testing can send them to CDC (Manifest Form, Appendix 3). Samples received by CDC will be analyzed for analytes related to e-cigarette use and lung injury.

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):

From data collected in the medical chart during routine care, clinicians or health department staff will abstract history of patients related to nicotine use, cannabis product use, vaping as mode of use and source of nicotine or cannabis product (Appendix 1). If shorter form (Appendix 2) is used, information of vaping behavior and substance used for vaping (i.e. nicotine, cannabis, or other products) is collected.

Clinical information/symptoms (describe):

Appendix 1 contains information on information on symptoms, diagnostic procedures, and treatment. Appendix 2 contains information on symptoms and treatment.

Contact information (describe):

Demographic information (describe):

Appendices 1 and 2 contain the following demographic data: age, sex, race, ethnicity

Environmental factors (describe):

Exposures (describe):

Appendices 1 and 2 include information on substances used

Medical history (describe):

Appendices 1 contains information on past medical history such as chronic illnesses.  
Appendices 1 and 2 contain information on 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 1 or 2 and 4 and 5).

Specimen/lab information (describe):

Appendix 3: Bronchoalveolar lavage (BAL) samples, blood and urine specimens are collected. BAL specimens are tested for lipids, phospholipids, mineral oil constituents, terpenes, vitamin E acetate, medium chain triglycerides, and cannabinoid and nicotine metabolites. Blood and urine specimens are tested for cannabinoid and nicotine metabolites

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: Peter Briss, MD

Title: Chief Medical Officer

Affiliation: NCCDPHP

**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: DDNID

Name: Althea Grant-Lenzy

Title: Senior Advisor for Science

**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:

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:***

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