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 # 2018002 - XXX **Date** 08/27/2018

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]*

Multistate outbreak of coccidioidomycosis (Valley fever) in U.S. students and adults who traveled to Tijuana area, Mexico

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

State:	Multiple States
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:	NYC Department of Health and Mental Hygiene
Name and Position Title:	Marci Layton, MD Assistant Commissioner, Bureau of Communicable Disease

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).*

Valley fever or coccidioidomycosis, is a respiratory fungal disease acquired by inhalation of the microscopic fungal spores which have been aerosolized through soil-disturbing activities such as digging. Untreated, coccidioidomycosis causes an illness lasting weeks to months. Antifungal medication reduces the duration and severity of symptoms. Appropriate medications, however, are often not prescribed because the infection is misdiagnosed as being of viral or bacterial etiology. People with compromised immune systems are at risk for life-threatening systemic infection from the fungus.

CDC received notification from New York City (NYC) Department of Health and Mental Hygiene

(DOHMH) on August 8, 2018, that two high school students (Patient 1 and 2) were hospitalized with pneumonia and persistent fevers following a service trip to Tijuana, Mexico. Students were in an area endemic for coccidioidomycosis and worked on housing projects that involved moving large amounts of soil. Both patients had a rash affecting the back, axilla, and groin. The illnesses were unresponsive to antibacterial medications, and a respiratory PCR panel (Biofire) was negative for a range of respiratory viruses, as were *Legionella* urinary antigen, blood cultures, and influenza testing. Both patients had chest X-rays showing bilateral patchy infiltrates that did not improve despite antibiotic treatment (the duration of antibiotic treatment is unknown). These findings are consistent with a fungal pneumonia.

Patient 1 traveled to the Tijuana area during July 8–15, 2018 as part of a group of 54 people from the same high school in NYC and ~10–15 people from Seattle, Washington. Patient 2 traveled to the area during July 15–22, 2018, with 22 people from the same high school as Patients 1 and 2 in NYC and ~30 people from Kansas City, Missouri.

In response to these illnesses, the NYC high school of Patient 1 and 2 notified the families in early August 2018 that students on the trip became ill with pneumonia and they should seek appropriate health care if any student or adult on the trip is experiencing any symptoms not restricted to Valley fever. After that notification, NYC DOHMH heard of two additional patients (Patients 3 and 4) with respiratory symptoms who both visited emergency departments but were not hospitalized.

All four illnesses were confirmed as caused by Valley fever by serologic testing, suggesting that an outbreak occurred, given shared exposure to dust-activities at the same site. Based on the severity of illness, high inoculum exposure is likely. The Missouri Health Department recently reported that a student from a Kansas City high school (a Kansas State resident) who traveled to Tijuana area in July 16–20, 2018 also tested positive for coccidioidomycosis. All the members of all the known groups who participated in this service trip during July 16–20, 2018 have been notified that some of the people have been hospitalized with Valley fever, and additional case finding is underway. To date, service trip volunteers have been identified in 4 states (NY, MO, KS, WA). In addition, we completed a binational notification to Mexico and the Mexican state of Baja California through the CDC US-Mexico Unit.

It is important to ensure that all travelers at risk of coccidioidomycosis from exposure at this site have been promptly notified to improve chances of timely proper diagnosis and treatment of infected persons. Better understanding the specific source of this outbreak could help protect future travelers to this area, as well as local residents, and prevent additional illnesses. The cases of coccidioidomycosis reported to date are of special concern because they manifested as severe illness in young, otherwise healthy people, suggesting that travelers were either exposed to massive doses of the pathogen, or infected by an unusually virulent strain.

CDC assistance with this investigation is requested to determine the scope and extent of the current cluster of Valley fever infections, identify potential common factors or risk factors among cases, and develop recommendations to potentially reduce the risk of additional cases. This package seeks to obtain OMB approval for a questionnaire (Appendix 1) to identify risk factors for and the source of infection. This information will be used to recommend potential prevention and control measures.

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):
Service trip volunteers who traveled to Tijuana area, Mexico in July 2018.

☐ Healthcare staff (describe):

☐ Laboratory staff (describe):

☒ Patients (describe):
Service trip volunteers who traveled to Tijuana area during July 2018 with laboratory confirmed Valley Fever infection.

☐ 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.*

Service trip volunteers who traveled to Tijuana area in July 2018 will be identified through local schools, health departments, and the volunteer organization that coordinated the trip. To date, service trip volunteers have been identified in 4 states (NY, MO, KS, WA).

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):
- ☐ Cross-sectional Study (describe):
- ☒ Cohort Study (describe):
  This is a cohort study to systematically collect information about clinical illness and potential exposures associated with Valley fever in order to identify cases and risk factors for and the source of infection.
- ☐ 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):
- ☐ Telephone Interview (describe):
- ☒ Self-administered Paper-and-Pencil Questionnaire (describe):
  We will contact service trip volunteers who traveled to Tijuana area, Mexico in July 2018 to complete the questionnaire (Appendix 1).
- ☐ Self-administered Internet Questionnaire (describe):
- ☐ Other (describe):

☐ Medical Record Abstraction (describe):

☐ 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):
Potential risk factors related to home building and dust exposure.

☒ Clinical information/symptoms (describe):
Clinical symptoms compatible with Valley fever among case patients.

☐ Contact information (describe):

☒ Demographic information (describe):
Sex, Age, Race, Ethnicity, State of residence

☐ Environmental factors (describe):

☒ Exposures (describe):
Information regarding exposures for case patients and non-cases.

☐ Medical history (describe):

☒ Risk factors (describe):
Potential risk factors related to home building, dust exposure, and travel history.

☐ Specimen/lab information (describe):

☒ Travel history (describe):
Specific dates of travel to Tijuana area, Mexico, and approximate previous travel to the area.

☐ Other (describe):

8. Duration of Data Collection (number of weeks):
3 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: Mitsuru Toda, MS, PhD

Title: EIS Officer

Affiliation: NCEZID/DFWED/MDB

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/DFWED/MDB

Name: Brendan Jackson, MPH, MD

Title: Team Lead

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, Brendan Jackson, 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: Brendan Jackson, MPH, MD

Date of Certification: 08/24/2018

Requested Approval Date (mm/dd/yyyy): *Instruction: Indicate the date by which approval is needed.*
08/29/2018