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 # 2020002 - XXX **Date** 01/24/2020

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]*

2019-nCoV Investigation, United States, 2020

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

State:	The first US cases have been confirmed in WA and IL. As of 1/24, persons are under investigation in 22 states, with additional investigations expected in more states the coming days and weeks. Over the course of the response we anticipate cases could be identified in any of the 50 states, District of Columbia, and the US territories. Jurisdictions 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:	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).*

Background

An outbreak of a novel coronavirus (2019-nCoV) in central China that is capable of causing severe illness has spread to multiple countries and infected hundreds of people, with case counts still climbing sharply. Cases have been reported in several regions of China, as well as Thailand, Japan, and South Korea. Human-to-human transmission of 2019-nCoV has been confirmed however it is currently unclear how easily or sustainably

this virus is spreading between people. The first US cases have been confirmed in WA and IL. As of January 24, 22 states have persons under investigation, and those numbers are expected to increase.

In response to this emergency, the Council of State and Territorial Epidemiologists (CSTE) has requested CDC assistance with a multi-state response to 2019-nCoV.

Objectives of Investigation

The objectives of the investigation are to identify cases and contacts of cases who are at risk for illness, understand the risk factors for disease and transmission, describe the clinical characteristics of disease, and identifying ways to control transmission. The data gathered from this investigation will be used to inform the U.S. public health response to 2019-nCoV and aid efforts to prevent and control the spread of the virus.

Investigation Planned

The data collection forms will provide critical information in this evolving epidemic—how the virus is transmitted, who is at risk, and what can be done to control 2019-nCoV's continued spread. This EEI GenIC requests OMB approval for the following forms:

- 2019-nCoV Case Report Form (Appx. 1): This form will provide information on nCoV cases, including demographic information, clinical presentation and course, medical history, 2019-nCoV laboratory testing, and exposure history.
- 2019-nCoV Patient Under Investigation (PUI) Form (Appx. 2): This form provides information on individuals who are under investigation as a potential 2019-nCoV case.
- 2019-nCoV Household/Close Contact Investigation Form (Appx. 3): This form provides information on close contacts of 2019-nCoV cases who are at risk for infection.

CDC will develop an investigation database that includes demographic, clinical, epidemiologic, and laboratory data; personal identifiers will be kept in secure CDC databases. Participation in the investigation is strictly voluntary.

Distinction from Air Travel Related 2019-nCoV Information Collections

This information collection is designed as an epidemiological investigation and is distinct from two travel-related information collections (CDC's 2019-nCoV Entry Risk Assessment Program and Aircraft Contact Investigation Protocol), which are aimed at identifying 2019-nCoV risks specifically among airline travelers.

The Entry Risk Assessment Program features enhanced public health entry risk assessments of travelers at select U.S. airports and is limited to information needed to make a public health risk assessment of a traveler from China with regard to illness and potential 2019-nCoV exposure. The Entry Risk Assessment Program is not designed or intended as a comprehensive case investigation form. It is intended for travelers only and used to flag potential cases and direct them to appropriate public health authorities for more in-depth investigation and medical evaluation if needed.

Similarly, the planned 2019-nCoV Aircraft Contact Investigation form will be used to collect identifying information on passenger and crew members who may have been exposed to a confirmed 2019-nCoV during air travel. The 2019-nCoV Aircraft Contact Investigation form collects identifying and location information of passengers and crew members exposed to 2019-nCoV in the aircraft environment and is not designed as a comprehensive assessment of close contacts of cases. This information will be shared securely with health departments in the states where they reside or are located (if international visitors).

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):
Cases (Appx. 1), patients under investigation (Appx. 2), close contacts of cases (Appx. 3)

☒ Healthcare staff (describe):
Health care workers who are close contacts. (Appx. 3)

☐ Laboratory staff (describe):

☒ Patients (describe):
Cases (Appx. 1) and patients under investigation (Appx. 2)

☐ 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.*

Potential respondents will be identified based on laboratory confirmation of n-CoV infection (cases, Appx. 1), patient under investigation criteria (PUI, Appx 2), and contacts of cases (close contacts, Appx 3). The CDC criteria for a 2019-nCoV patient under investigation (PUI) have been developed based on what is known about MERS-CoV and SARS-CoV and are subject to change as additional information becomes available. PUIs are determined based on clinical features (i.e., fever and symptoms of lower respiratory illness) and epidemiologic risk (i.e., travel to Wuhan, China, close contact with a PUI or confirmed case of 2019-nCov within last 14 days). PUIs will be reported to state health departments, which will then be communicated to CDC. Contacts are identified as individuals in the same household or in close personal contact with the case.

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):
Data will be collected to identify the epidemiology of nCoV disease transmission, clinical presentation and progression, and risk factors among cases, PUIs, and contacts (Appx. 1, 2, and 3)

☐ Cross-sectional Study (describe):

☐ Cohort Study (describe):

☐ Case-Control Study (describe):

☐ Other (describe):

☐ Environmental Assessment (describe):

☒ Laboratory Testing (describe):
Specimens will be collected from cases and PUIs (Appx. 1 and 2)

☐ 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):
Federal, state, or local public health officials will interview cases (Appx. 1), PUIs (Appx. 2), and case contacts (Appx. 3).

☐ Telephone Interview (describe):

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

☐ Self-administered Internet Questionnaire (describe):

☐ Other (describe):

☐ Medical Record Abstraction (describe):

☒ Biological Specimen Sample
Specimens for this investigation will be collected from cases and PUIs for laboratory testing for 2019-nCoV as part of routine care (Appx. 1, 2).

☐ 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):
Case, PUI, and contact forms include questions about exposure history, medical history, activity in preceding weeks, and other potential risk factors (Appx. 1, 2, 3)

☒ Clinical information/symptoms (describe):
Clinical presentation or presence of respiratory symptoms (Appx. 1, 2, 3).

☒ Contact information (describe):
Contact information necessary for case investigation and contact investigations (Appx. 1, 2, 3).

☒ Demographic information (describe):
Name, date of birth, race, ethnicity (Appx 1, 3) sex, residence, and other demographic details (Appx. 1, 2, 3).

☐ Environmental factors (describe):

☒ Exposures (describe):
Information regarding exposure risk factors, including travel and contacts (Appx. 1, 2, 3)

☒ Medical history (describe):
Symptom presentation, medical conditions, medication history. (Appx. 1, 2, 3)

☒ Risk factors (describe):
The investigation will identify epidemiologic and clinical risk factors for disease and transmission (Appx. 1, 2, 3)

☒ Specimen/lab information (describe):
2019-nCoV diagnostic testing (Appx. 1, 2), respiratory diagnostic results (Appx. 2)

☒ Travel history (describe):
Travel within US and outside US (Appx. 1, 2, 3)

☐ 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:	Dan Jernigan, M.D., M.P.H.
Title:	Incident Manager
Affiliation:	CDC - National Center for Immunization and Respiratory Diseases

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:	NCIRD/OD
Name:	Sam Posner

Title:	Deputy Director for Science

shp5@cdc.gov; 770.488.6398

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, Sam Posner, 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:	Sam Posner
Date of Certification:	01/24/2020

Requested Approval Date (mm/dd/ivy): *Instruction: Indicate the date by which approval is needed.*
01/24/2020

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
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