

**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

CLEARANCE 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). <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]*

Contact Investigation of Travelers Potentially Exposed to Middle East Respiratory Syndrome Coronavirus (MERS-CoV) during Air Travel

LOCATION OF INVESTIGATION: *Instruction: Indicate location where investigation will occur. If multiple locations, specify each one.*

State:

City/County (if applicable)

Country

REQUESTING AGENCY: *Instruction: Indicate name of agency requesting epidemiological assistance and the name and position title of the requestor*

Agency:

Name and Position Title:

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. At a minimum, please provide the following information: 1) background necessary to understand the importance of the outbreak or event; 2) justification of the need for an investigation, including a description of any data already available or data gaps that exist; 3) justification as to why this issue requires an urgent response; and 3) an explanation of how the information collected will be used to inform prevention and control measures. Use as much space as necessary (suggested length: 250-500 words).*

Middle East Respiratory Syndrome (MERS) is viral respiratory illness first reported in Saudi Arabia in 2012. It is caused by a coronavirus called MERS-CoV. Most people who have been confirmed to have MERS-CoV infection developed severe acute respiratory illness. They had fever, cough, and shortness of breath. About 30% of these people died. A second imported case of MERS in the United States, identified in a traveler, was reported to CDC by the Florida Department of Health on May 11, 2014, and confirmed by CDC on May 11. On May 1, the patient traveled by commercial airline from Saudi Arabia to the UK, then UK to Boston, Massachusetts; then Boston to Atlanta, Georgia; and then Atlanta to Orlando, Florida. The traveler was a health-care provider in Saudi Arabia and traveled while symptomatic and potentially contagious. Little is known about the modes of transmission of MERS-CoV and the risks of acquiring infection from contact with an infected person, either in the community or household setting or on conveyances such as planes, buses or trains. Many of the contacts on the Boston to Atlanta leg of the journey ended their travel in Georgia. The Georgia Department of Health has requested CDC assistance in doing a contact investigation to identify those passengers and notify them about the possible exposure. This will include collecting information about any symptoms related to MERS-CoV infection and collection of appropriate biological specimen to test for MERS-CoV.

The objectives of this investigation are to:

1. Notify and provide information to passengers and crew potentially exposed to MERS-CoV
2. Detect symptomatic contacts
3. Refer symptomatic contacts for medical evaluation and management
4. Describe the occurrence and extent of transmission of MERS-CoV to passengers or crew on the flight to assess risk of transmission on flight

Overview of investigation

The investigation will entail a descriptive epidemiologic study of the 93 contacts of the MERS-CoV case patient. Data will be collected from MERS-CoV contacts via initial telephone interview (Attachment A) and follow-up interview (Attachment B). The follow-up interview will be administered to MERS-CoV contacts after the incubation period (about 14 days) to determine if exposed persons are still symptom free. The investigation also will include collection of biological specimen (specifically, blood will be collected for acute and convalescent sera and, among those who are symptomatic, oral and nasopharyngeal swabs will be taken and tested for MERS-CoV infection); collection of samples will be coordinated by the GA Dept of Health and specimens will be sent to CDC for testing. As the investigation progresses, based on feedback during interview, the questionnaires (Attachments A and B) might be modified in the field or new questionnaires might be developed as new information about exposures or risk factors are identified.

Simple frequencies of the proportion of persons identified with respiratory symptoms, and the proportion of those who have a positive test for MERS-CoV, along with the proportion positive among all participants (assuming there is asymptomatic infection), will be calculated. Contact investigation data will be analyzed to determine the occurrence and extent of MERS-CoV transmission among case contacts, to identify risk factors for transmission, and to implement immediate control measures for any new infectious cases identified. Characterization of MERS-CoV transmission also will be used to inform public health prevention and control recommendations for travel restriction among persons with symptoms consistent with MERS-CoV.

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):

Contacts of the MERS-CoV case patient

- Healthcare staff (describe):

- Laboratory staff (describe):

- Patients (describe):

Persons admitted to hospital with confirmed MERS-CoV infection or with symptoms consistent with MERS-CoV infection

- Restaurant staff (describe):

Other (Travelers on conveyances):

Airline passengers and staff

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.*

Respondents will be identified by reviewing airline manifests, plane sale records, hospital rosters, and information provided by the case patients about other household and community contacts.

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):

Describe the occurrence and extent of transmission of MERS-CoV related to the exposure of passengers or crew on air or land conveyances or community, household or community contacts in order to assess factors related to transmission. Contact investigation data will be analyzed to determine the occurrence and extent of MERS-CoV transmission among case contacts, to identify risk factors for transmission, and to implement immediate control measures for any new infectious cases identified. Characterization of MERS-CoV transmission also will be used to inform public health prevention and control recommendations for travel restriction among persons with symptoms consistent with MERS-CoV.

Cross-sectional Study (describe):

Cohort Study (describe):

Case-Control Study (describe):

Other (describe):

Environmental Assessment (describe):

Laboratory Testing (describe):

Blood for acute- and convalescent-phase sera among all contacts and possibly for PCR among asymptomatic persons. Oral and nasopharyngeal swabs and other appropriate samples for MERS-CoV testing among symptomatic contacts.

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 (All Contacts):

Identified contacts will be interviewed by telephone to assess information about flight/travel, travel companions, and health status (Attachment A and B).

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

Self-administered Internet Questionnaire (describe):

Other (describe):

Medical Record Abstraction (Contacts admitted with respiratory symptoms consistent with MERS-CoV infection):

If persons are admitted to a hospital for confirmed MERS-CoV or symptoms consistent with MERS-CoV, the investigation will include medical record abstraction to obtain relevant clinical information. The abstraction form will be developed in the field if potential or confirmed cases admitted to a hospital are identified during contact investigation.

Biological Specimen Sample (Contacts admitted with respiratory symptoms consistent with MERS-CoV infection):

Blood for acute- and convalescent-phase sera among all contacts and possibly for PCR among asymptomatic persons. Oral and nasopharyngeal swabs and other appropriate samples for MERS-CoV testing among symptomatic contacts.

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 (All contacts):

If a contact also traveled to the Arabian Peninsula, activities and exposures such as to contacts and foods ate while in that region

Clinical information/symptoms (All contacts):

Symptoms consistent with MERS-CoV infection: fever, cough, difficulty breathing

Contact information (Contacts of symptomatic contacts):

Known contacts of other ill persons before illness. History of known travel. Heathcare, community, or household contacts since illness.

Demographic information (All contacts):

Age, gender, race and ethnicity, country of birth, country of residence

Environmental factors (describe):

Exposures (All contacts):

Animal exposures

 Medical history (Symtomatic contacts):

Relevant past medical history particularly of immunosuppressive conditions or medications

 Risk factors (describe): Specimen/lab information (Symptomatic contacts):

Blood and oral and nasopharyngeal swabs and other appropriate samples

 Travel history (All contacts):

History of travel to countries with reported MERS-CoV transmission in the Arabian Peninsula and neighboring countries

 Other (describe):

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

12 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**INVESTIGATION LEAD:** *Instruction: Indicate the name, title, and affiliation of the person who will be leading the investigation.*

Name: Nicki Pesik

Title: Branch Chief

Affiliation: Quarantine and Border Health Services Branch, DGMQ

CDC SPONSORING PROGAM 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/DGMQ

Name: Clive M Brown

Title: Associate Director for Science

Contact Information: *Provide complete contact information. Check box for preferred method(s) of contact during the OMB approval process.* Office phone: (404)639-3952 Home phone: Cell/Mobile: E-mail: cmb8@cdc.gov

Other:

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), Danice Eaton.

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

For internal use. Do not complete.

Date/Time received by ICRL

Date/Time submitted to OMB

Date/Time approved
