

**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). <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]*

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 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).*

infection control measures. The initial work-up included a negative malaria smear. The patient is receiving intravenous fluids and having moderate fluid losses through vomiting and diarrhea. A blood specimen was sent to the Texas State Public Health Laboratory and CDC for Ebola RT-PCR testing on September 29, 2014. RT-PCR results from the CDC Viral Special Pathogens Branch laboratory were reported as positive on September 30, 2014, and a diagnosis of EVD was made.

On September 30, 2014, TDSH requested assistance from CDC to investigate this case, to assess the risk of potential spread from the patient to household, community, conveyance and hospital contacts, to identify other possible contacts, and to provide recommendations on appropriate infection control measures to prevent virus transmission as part of the coordinated response efforts.

The investigation will follow a case series study design, where case report forms (see Appendix 1) will be collected for every patient meeting the case definition criteria (see Item 4 below). Relevant clinical data, including the patient's date of onset, date of death, hospitalization, and contacts that the patient had prior to developing illness all are collected, in an effort to determine the risk factors that led to this patient's infection. A separate contact tracing form (see Appendix 2) is completed to collect information of people who had direct unprotected contact with the patient while they were ill and prior to isolation in a health facility. These contacts are then followed daily for onset of fever and other EVD symptoms, and will be investigated as cases and treated under barrier nursing precautions if they develop illness. Contact follow-up might extend beyond Texas if contacts are outside the state once they are identified.

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):

Persons who exhibit symptoms consistent with the case definitions of EVD or are at risk for infection (See Item 4 below)

Healthcare staff (describe):

Healthcare staff who exhibit symptoms consistent with the case definitions of EVD or are at risk for infection (See Item 4 below)

Laboratory staff (describe):

Laboratory staff who exhibit symptoms consistent with the case definitions of EVD (See Item 4 below)

Patients (describe):

Persons who exhibit symptoms consistent with the case definitions of EVD or are confirmed cases (See Item 4 below)

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.*

Respondents are selected on the basis of meeting case definition criteria and exposure level criteria. Cases are categorized as persons under investigation (PUI), probable case, or confirmed case. A high risk exposure level includes any of the following: percutaneous (e.g., needle stick) or mucous membrane exposure to blood or body fluids of EVD patient, direct skin contact with, or exposure to blood or body fluids of, an EVD patient without appropriate personal protective equipment (PPE), processing blood or body fluids of a confirmed EVD patient without appropriate PPE or standard biosafety precautions, or direct contact with a dead body without appropriate PPE in a country where an EVD outbreak is occurring. Low risk exposures include any of the following: household contact with an EVD patient, or other close contact with EVD patients in health care facilities or community settings.

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):

- The investigation will follow a case series study design, where case report forms (see Appendix 1) will be collected for every patient meeting the case definition criteria (see Item 4).

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):

Interview potentially exposed persons, cases and their contacts, as needed

Telephone Interview (describe):

Interview potentially exposed persons, cases and their contacts, as needed

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

Self-administered Internet Questionnaire (describe):

Other (describe):

Medical Record Abstraction (describe):

Hospital records may be used to collect relevant clinical information

Biological Specimen Sample

Blood or other specimens will be collected from patients to confirm or rule out Ebola virus infection.

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):

Risk factors prior to becoming ill such as caring for other sick individuals, traveling, recent hospital visits, etc. are all assessed.

Clinical information/symptoms (describe):

Date of symptom onset and the presence/absence of several symptoms of disease, hospitalization information, and disease outcome (fatal/survival).

Contact information (describe):

The phone number, address, and email of the patient or their family member, head of household is collected.

Demographic information (describe):

Occupation is collected, sex, age, race/ethnicity, and residential information.

Environmental factors (describe):

Exposures (describe):

Risk factors prior to becoming ill such as caring for other sick individuals, traveling, recent hospital visits, etc. are all assessed.

Medical history (describe):

Risk factors (describe):

Risk factors prior to becoming ill such as caring for other sick individuals, traveling, recent hospital visits, etc. are all assessed.

Specimen/lab information (describe):

Diagnostic laboratory testing results for Ebola infections are collected

Travel history (describe):

Both travel prior to illness and travel during illness is collected.

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: John Brooks

Title: Medical Epidemiologist

Affiliation: NCHHS/TP/EB

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/DHCPP/Viral Special Pathogens Branch

Name: Stuart Nichol

Title: Chief, Viral Special Pathogens Branch

Contact Information: bknust@cdc.gov, 404-639-1104 email preferred

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: Stuart Nichol

Date of Certification: 9/30/2014

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

10/1/2014

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
2400 Century Center, MS E-92
Office: 404.498.6389
Deaton@cdc.gov

For internal use. Do not complete.

Date/Time initial GenIC received
by ICRL

9/22/2014, 4:48PM

Date/Time final GenIC received
by ICRL

Date/Time submitted to OMB

Date/Time approved