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 # 2014016 - XXX **Date** 9/2/2014

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]*

Undetermined Sources and Risk Factors for an Ebola Hemorrhagic Fever Outbreak—Democratic Republic of Congo, 2014

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

State:	Equateur Province
City/County (if applicable)	
Country	Democratic Republic of Congo

Requesting Agency: *Instruction: Indicate name of agency requesting epidemiological assistance and the name and position title of the requestor*

Agency:	Ministry of Health, Democratic Republic of Congo
Name and Position Title:	Dr. Felix Kabange Numbi Mukwampa, Minister of Health

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).*

On August 24, 2014, the DRC Ministry of Health (MoH) announced an Ebola outbreak in Boende Health Zone, Tshuapa District, Equateur Province. As of August 28, 24 cases of suspect Ebola hemorrhagic fever (EHF) have been identified, including 13 deaths (case fatality rate of 54%). Eight blood specimens from suspect cases were sent to the National Institute for Biomedical Research (INRB) in Kinshasa and to the International Centre for Medical Research of Franceville (CIRMF) in Gabon for testing. INRB confirmed Ebola virus in 4/8 specimens and CIRMF confirmed Ebola virus in 6/8 specimens. Zaire ebolavirus is the causative species. DNA sequencing results are pending to confirm that this is a different strain of Zaire ebolavirus from the strain currently circulating in West Africa.

On August 29, 2014, the DRC MoH requested assistance from the CDC to halt and prevent virus transmission as part of the coordinated response efforts.

The objectives of the investigation are to collect necessary suspected case and contact information from all affected villages and areas. The investigation will follow a case series study design, where case report forms (see Appendix 1) will be collected for every patient meeting the suspect case definition criteria (see Item 4 below). Forms are collected through interview of patients or family members if patients have died or are infants, in either French or the local language. Relevant clinical data, including the patient's date of onset, date of death, hospitalization and funeral information, 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. If diagnostic testing confirms that this patient has EVD, a separate contact tracing form (see Appendix 2) is completed to collect information regarding people who had direct unprotected contact with the patient while they were ill and prior to treatment in a facility with barrier nursing. 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.

Ebola virus outbreaks disproportionately affect healthcare workers, assessment infection control within the healthcare system will be needed. We also will assess communications strategies aimed at educating health workers, volunteers, and community members. These actions will be necessary to interrupt transmission of disease from person-to-person. Recommendations to improve infection control and communication strategies will be made to help prevent further transmission of the virus. These assessments will be made through observation and review of existing information. If additional data are needed, data collection forms will be developed in the field.

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 (See Item 4 below)

☒ Healthcare staff (describe):

Healthcare staff who exhibit symptoms consistent with the case definitions of EVD (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):

Patients who exhibit symptoms consistent with the case definitions of EVD (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. Cases are categorized into one of three case definitions: suspected (alive or dead person with fever and at least three additional symptoms, or fever and a history of contact with a person with hemorrhagic fever or a dead or sick animal, or unexplained bleeding); probable (meets the suspected case definition and has an epidemiologic link to a confirmed or probable case); confirmed (suspected or probable case that also has laboratory confirmation).

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 suspect case definition criteria (see Item 4). Information about contacts of confirmed cases will be collected using the contact tracing form (see Appendix 2).

☐ Cross-sectional Study (describe):

☐ Cohort Study (describe):

☐ Case-Control Study (describe):

☐ Other (describe):

☐ Environmental Assessment (describe):

☒ Laboratory Testing (describe):

When possible, diagnostic testing will be used to confirm Ebola virus infection or rule out infection. Laboratory testing will not be performed by CDC personnel, but laboratory results will be recorded.

☐ 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):

The case report form (Appendix 1) and contact listing form (Appendix 2) will be completed by face-to-face interview.

☐ Telephone Interview (describe):

☐ 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 in the case report form

☒ Biological Specimen Sample

Blood or oral swab specimens will be collected from patients to confirm or rule out Ebola virus infection. Laboratory testing will not be performed by CDC personnel, but laboratory results will be recorded.

☐ 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, attending & participating in funerals, traveling, recent hospital visits, consulting spiritual or traditional healer, and zoonotic contacts 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 of the patient or their family member, head of household is collected.

☒ Demographic information (describe):

Occupation is collected, sex, age, and residential information.

☐ Environmental factors (describe):

☒ Exposures (describe):
Risk factors prior to becoming ill such as caring for other sick individuals, attending & participating in funerals, traveling, recent hospital visits, consulting spiritual or traditional healer, and zoonotic contacts are all assessed.

☐ Medical history (describe):

☒ Risk factors (describe):
Risk factors prior to becoming ill such as caring for other sick individuals, attending & participating in funerals, traveling, recent hospital visits, consulting spiritual or traditional healer, and zoonotic contacts are all assessed.

☒ Specimen/lab information (describe):
Diagnostic laboratory testing results for viral hemorrhagic fever 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):
Unknown, but the investigation will continue for at least 2-3 months.

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:	Andrea McCollum
Title:	Epidemiologist
Affiliation:	NCEZID / DHCPP /PRB

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:	Barbara Knust
Title:	Epidemiologist

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

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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:	Barbara Knust
Date of Certification:	

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

9/5/2014

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	8/30/2014, 1:29PM
Date/Time final GenIC received by ICRL	9/2/2014, 8:46AM
Date/Time submitted to OMB	9/2/2014, 12:15PM
Date/Time approved	
