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 # 2015009 - 028 **Date** 06/12/2015

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 source, mode of transmission and risk factors for a Widespread Outbreak of Cholera among residents of multiple counties — Kenya, 2015

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

State:	
City/County (if applicable)	Multiple counties
Country	Kenya

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

Agency:	Kenya Ministry of Health
Name and Position Title:	Dr. Nicholas Muraguri, Director of Medical Services

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).*

An multi-county outbreak of cholera in Kenya has caused over 4,000 cases across the country since the beginning of 2015. From ~January 1, 2015 to date, a total of 4,131 cases of cholera have been reported, of which 259 have been laboratory confirmed as *Vibrio cholerae* O1. Presently, 76 deaths have been reported. At least 14 of the 47 counties in Kenya have reported cases with a range in case fatality proportions from <1% to 6.6%. Highly affected counties include Nairobi, Nakuru, Muranga, Kirinyaga, Embu and Homa Bay. Nairobi county continues to have new cases detected in the infomal settlements of Kibera, Mukuru Kayiaba, Mukuru Reuben, Kawangware, and Mukuru Kwa Njenga. CDC-Atlanta Enteric Diseases Laboratory Branch has confirmed a number of isolates from this outbreak as *Vibrio cholerae* O1 biotype El Tor, serotype Ogawa with susceptibility to doxycycline and resistance to nalidixic acid and furazolidone, and reduced susceptibility to ampicillin and ciprofloxacin.

The Kenyan Ministry of Health (MoH) in partnership with the Field Epidemiology and

Laboratory Training Program (FELTP) are investigating the outbreak and implementing ongoing response efforts. On June 3, 2015, the Kenya MoH contacted CDC to request assistance with the epidemiological and laboratory investigation of this ongoing and widespread cholera outbreak.

The objectives of the investigation are to provide technical assistance to the Kenyan Ministry of Health with the investigation of an outbreak of cholera in multiple counties of Kenya. This will involve a) conduct a community questionnaire to assess risk factors for transmission, and knowledge, attitudes and practices of cholera transmission and prevention b) evaluating the outbreak response to date; c) reviewing surveillance and laboratory data, and prevention measures, and make recommendations for preventing further transmission; d) evaluating of how changes in the public health structure in Kenya (i.e. decentralization) may have affected efforts to respond to the outbreak and prevent its spread; e) CDC will assist with the laboratory investigation to include culture, antimicrobial susceptibility patterns, sub-typing, and whole genome sequencing for *Vibrio cholerae* O1 in de-identified clinical and environmental samples. Specimen collection, storage, and transport will be done according to local procedures and protocols. Should the Ministry of Health require any future research of banked specimens a specific research ptotocol will be developed and sumbitted for Institutional Review Board determination.

The planned investigation will describe the cholera outbreak both epidemiologically and in the laboratory context for making recommendations for controling the outbreak and preventing further spread of cholera. Cholera is a notifiable disease in Kenya and as such the data is collected and maintained by the Ministry of Health. Retrospective and prospectively collected surveillance and laboratory data collected by the Ministry of Health will be analysed. In addition, questionnaires will be administered to a random selection of households, and healthcare workers at facilities treating cholera patients in a number of affected counties. These data combined will be used to evaluating the outbreak response.

The questionnaires will be administered in-person to community members at their homes (Appendix 1 - English Version) or to health facility staff at health facilities (Appendix 2 - English Version). Standardized questionnaires will be administered by trained Kenyan enumerators to assess risk factors for transmission, and knowledge of cholera transmission and prevention, and for health care workers to assess knowledge regarding the physical signs and treatment of dehydration, hygiene, and treatment practices such as the administration of intravenous fluids and oral rehydration salts. CDC also will assist with the laboratory investigation to include whole genome sequencing for *Vibrio cholerae* O1 in de-identified clinical from cholera patients and environmental samples (e.g. water or food). All patient samples will be collected by either the Kenya Ministry of Health or by healthcare workers as part of a patient's course of care. CDC will not collect patient clinical samples. CDC investigators will not have access to personally identifiable laboratory data, nor will they have access to any other identifying information. Informed consent will be obtained from all survey respondents.

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):

Adult community members ≥18 years old will be interviewed to assess risk factors for transmission, and knowledge, attitudes and practices of cholera transmission and prevention. (Appendix 1)

☒ Healthcare staff (describe):

Health care workers will be interviewed to assess knowledge regarding the physical signs and treatment of dehydration, hygiene, and treatment practices such as the administration of intravenous fluids and oral rehydration salts. (Appendix 2)

☐ Laboratory staff (describe):

☐ Patients (describe):

☐ 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.*

Villages within affected counties that met pre-defined criteria will be randomly selected in a number of affected counties. In turn, participants in the community will be randomly selected using an electronic random number generator from available lists of village residents/census information. The exact methodology will be determined in collaboration with the Ministry of Health during the investigation.

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):

To describe the epidemiology of the outbreak, and assess the response capabilities in order to to make recommendations for controling the outbreak and preventing further spread of cholera

☐ Cross-sectional Study (describe):

☐ Cohort Study (describe):

☐ Case-Control Study (describe):

☐ Other (describe):

☐ Environmental Assessment (describe):

☒ Laboratory Testing (describe):

Clinical or environmental specimens collected will be forwarded to CDC- Enteric Diseases Laboratory Branch for culture, antimicrobial susceptibility patterns, sub-typing, and whole genome sequencing for *Vibrio cholerae* O1 in de-identified clinical and environmental samples. Clinical specimens of cholera patients will be collected by either the Kenya Ministry of Health or by healthcare workers as part of a patient's course of care. All specimen collection, storage, and transport will be done according to local procedures and protocols.

☐ 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):

We will interview adult community members ≥18 years old and health care providers (medical officers, clinical officers, and nurses). For community members we will ask to speak to the person in the home who usually takes care of the ill family members and brings the water for the family.

☐ Telephone Interview (describe):

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

☐ Self-administered Internet Questionnaire (describe):

☐ Other (describe):

☐ Medical Record Abstraction (describe):

☒ Biological Specimen Sample

Clinical specimens will be collected from suspect cholera patients, that is patients with acute watery diarrhea. Specimens will be collected by either the Kenya Ministry of Health or by healthcare workers as part of a patient's course of care. The specimens collected will be forwarded to CDC- Enteric Diseases Laboratory Branch for culture, antimicrobial susceptibility patterns, sub-typing, and whole genome sequencing for *Vibrio cholerae* O1 in de-identified clinical and environmental samples. CDC will not collect any clinical specimens from cholera patients.

☒ Environmental Sample:

With Ministry of Health approval, environmental samples (e.g. water or food) may be forwarded to CDC-Waterborne Diseases Prevention Branch, Environmental Laboratory for confirmatory testing, if this capability does not currently exist in country. .

☐ 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):
Questions regarding water sanitation and hygiene practices

☒ Clinical information/symptoms (describe):
Description of symptoms, physical signs and treatment practices

☐ Contact information (describe):
Not needed

☒ Demographic information (describe):
Age, sex, tribe, education level, profession

☒ Environmental factors (describe):
water sanitation and hygiene questions

☒ Exposures (describe):
Water, food, person to person, ill contacts, sewage

☐ Medical history (describe):

☒ Risk factors (describe):
Age, sex, education level, type of food consumed, sources of water consumed

☐ Specimen/lab information (describe):

☒ Travel history (describe):
Where travel took place within and outside the country

☐ Other (describe):

8. Duration of Data Collection (number of weeks):
4 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:	Ciara O'Reilly
Title:	Epidemiologist
Affiliation:	CDC/NCEZID/DFWED/WDPB

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:	CDC/NCEZID/DFWED/WDPB
Name:	Ciara O'Reilly
Title:	CDC/NCEZID/DFWED/WDPB

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, Ciara O'Reilly, 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:	Ciara O'Reilly
Date of Certification:	6/12/2015

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

6/16/2015

E-mail the completed form to the Information Collection Request Liaison (ICRL) or EIS program ICRL designee.

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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	
Date/Time final GenIC received by ICRL	
Date/Time submitted to OMB	
Date/Time approved	
