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 # 2015005 - XXX **Date** 01/22/2015

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 risk factors for severe illness and death among funeral attendees — Mozambique, 2015

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

State:	Tete Province
City/County (if applicable)	Chitima
Country	Mozambique

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

Agency:	Mozambique National Institute of Health
Name and Position Title:	Dr. Ilesh V. Jani, Director, Mozambique National Institute 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 January 12th, 2015, an outbreak of severe illness and fatalities was reported among people who attended a funeral on January 9th, 2015 in Tete Province, Mozambique. To date, 73 deaths and 177 cases have been reported by the Ministry of Health. The illness has affected men, women, and children of different ages, with the youngest case occurring in a 2 year old child. Initial field investigation by the National Institute of Health in Mozambique suggests that the illness may have resulted from consumption of a traditional beverage, and that the illness is most likely due to a chemical toxin. Because of a potential environmental etiologic agent, the Mozambique Ministry of Health requested the assistance of the National Center for Environmental Health/Agency for Toxic Substances and Disease Registry in investigating the cause of illnesses and fatalities associated with attendance at the funeral event.

The objectives of this investigation are to assist the Mozambique Ministry of Health in the following:
1) Identify the cause of the outbreak;

2) Confirm route of exposure;
3) Determine the risk factors for illness and death;
4) Divison of Laboratory Sciences will participate.

The planned investigation will begin with a descriptive study of affected funeral attendees (n=250) to identify potential risk factors and exposures of interest. The characteristics of the persons affected will be described. The questionnaire (Appendix 1 - Engish Version; Appendix 2 - Portuguese Version) will be administered in-person to attendees or family member proxies at their homes or in the hospital. CDC also will assist with a toxicological investigation to include testing of previously collected (by Mozambique National Institute of Health) de-identified environmental and biological samples from case patients for potential etiologies as needed. CDC investigators will not have access to personally identifiable laboratory data, nor will they have access to any identifying keys.

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):

Funeral attendees or their proxy (family members or neighbors) for people who have died or are too ill to respond will be interviewed (Appendices).

☐ Healthcare staff (describe):

☐ Laboratory staff (describe):

☒ Patients (describe):

Hospitalized funeral attendees will be interviewed (Appendices).

☐ 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.*

Case patients will be identified by interviews in the community and hospital chart review

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 describing the demographic characteristics, risk factors, and potential

exposures of the people who became ill will be collected.

☐ Cross-sectional Study (describe):

☐ Cohort Study (describe):

☐ Case-Control Study (describe):

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☐ Other (describe):

☐ Environmental Assessment (describe):

☒ Laboratory Testing (describe):

CDC will assist with a toxicological investigation to include testing of previously collected (by Mozambique National Institute of Health) de-identified environmental and biological samples from case patients for potential etiologies as needed. CDC investigators will not have access to personally identifiable laboratory data, nor will they have access to any identifying keys. Because these samples already have been collected by Mozambique National Institute of Health, there are no respondents to this component of the investigation.

☐ 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 funeral attendees or their proxy (if attendee is unable to respond)

☒ Telephone Interview (describe):

We will interview funeral attendees or their proxy (if attendee is unable to respond)

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

☐ Self-administered Internet Questionnaire (describe):

☐ Other (describe):

☐ Medical Record Abstraction (describe):

☐ Biological Specimen Sample

☐ 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):
Types of food and beverage consumed and when, funeral attendance

☒ Clinical information/symptoms (describe):
Weight/height, Description of symptoms, hospital course, final disposition

☒ Contact information (describe):
Address, phone numbers in order to conduct interviews

☒ Demographic information (describe):
Age, sex, race, marital status, profession, educational level

☒ Environmental factors (describe):

☒ Exposures (describe):

☒ Medical history (describe):
Underlying medical conditions, medication history

☒ Risk factors (describe):
Age, sex, race, types of food/beverage consumed

☐ Specimen/lab information (describe):

☐ Travel history (describe):

☐ 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:	Dr. Amelia Kasper
Title:	EIS Officer
Affiliation:	NCEH/ONIEH/DEHHE/HSB

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:	NCEH/ONIEH/DEHHE/HSB
Name:	Dr. Joshua Schier
Title:	Medical Officer, Environmental Toxicology Team Lead

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:	Joshua Schier, MD, MPH
Date of Certification:	01/21/2015

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

01/23/2015

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	1/22/15; 5:00PM
Date/Time final GenIC received by ICRL	
Date/Time submitted to OMB	
Date/Time approved	
