

**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]*

Undetermined burden of disease and risk factors for chikungunya virus infections—Puerto Rico, 2014

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).*

Chikungunya virus is a mosquito-borne alphavirus that can cause large outbreaks of acute febrile illness with polyarthralgia. In December 2013, the World Health Organization reported the first local transmission of chikungunya virus in the Western Hemisphere, with autochthonous cases identified in Saint Martin. Since then, local transmission has been identified in 17 countries or territories in the Caribbean or South America. As of June 6, 2014, a total of 130,941 suspected and 4,486 laboratory-confirmed chikungunya cases had been reported from these areas. On May 19, the first laboratory-confirmed chikungunya case was reported in the United States territory of Puerto Rico. Starting on May 15, the case-patient, a 16-year-old female, experienced an acute febrile illness with large joint pain. She did not report travel outside Puerto Rico in the two weeks before her illness began. Subsequent investigation by Puerto Rico Department of Health (PRDH) identified 2 additional laboratory-confirmed chikungunya cases in the area surrounding the case-patient's

residence in the Rio Piedras neighborhood of San Juan. Since the first chikungunya case was detected, 25 additional laboratory-confirmed cases have been identified in Puerto Rico, of which four had travel history to the Dominican Republic, and all resided in the San Juan metropolitan area with the exception of one that resided in Patillas in southeastern Puerto Rico. As has recently occurred in many other regions of the Caribbean, the number of chikungunya cases detected in Puerto Rico may increase rapidly. The Department of Health is requesting assistance to conduct household investigations, establish sentinel surveillance in health care centers, assist with education of healthcare providers and the public, and provide recommendations for vector control and other mitigation efforts.

The EpiAid Team in collaboration with PRDH will: 1) Conduct cluster investigations around the case-patients' homes. Information obtained will include: a) detection of chikungunya cases that would not otherwise have been detected by passive surveillance; b) identification of the health care-seeking behaviors of patients; c) description of the clinical spectrum of disease across age groups; d) estimation of the level of DENV circulation in areas with known CHIKV transmission; e) entomologic surveillance to determine vector density and the frequency with which adult mosquitoes are infected with DENV and/or CHIKV; and f) identification of household and individual risk factors for infection with CHIKV.

2) Establish sentinel chikungunya surveillance sites. Because most chikungunya case-patients are likely to only need out-patient care, we will establish 7-10 sentinel surveillance sites in outpatient clinics and emergency departments to detect acute febrile illnesses consistent with chikungunya. These sites along with data from the sentinel enhanced dengue surveillance system (SEDSS) will enable tracking of the outbreak and estimation of disease incidence.

3) Provide messaging, alerts and educational material for clinicians and the public.

4) Provide recommendations on vector surveillance and control mechanisms to monitor and mitigate the mosquito vectors that transmit CHIKV.

5) Conduct a rapid assessment of hospital needs to ensure availability of necessary medications (IV fluids, pain medication, antipyretics, etc.).

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):

Household members and neighbors of laboratory-confirmed chikungunya case-patients will be contacted and offered participation in the investigation, including answering a questionnaire (Appendices 1 and 2) and diagnostic testing for chikungunya and dengue.

Healthcare staff (describe):

Healthcare providers might be interviewed, or medical records abstracted, to obtain initial clinical information on cases to be recorded on the dengue/chikungunya case

investigation form (Appendix 3).

Laboratory staff (describe):

Patients (describe):

Residents of Puerto Rico with laboratory-confirmed chikungunya.

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.*

Patients will be identified when they present to medical care with and are reported to PRDH as having an illness clinically compatible with chikungunya (i.e., fever and arthralgia/arthritis). Such cases will be reported using the dengue/chikungunya case reporting form (Appendix 3). Household investigations conducted around the residences of laboratory-confirmed chikungunya is expected to identify additional cases with chikungunya in the same household or neighborhood.

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):

Establish sentinel surveillance for chikungunya, and perform household investigations to identify demographic, geographic, or behavioral risk factors for infection, health care-seeking behaviors of infected individuals, and clinical awareness and diagnosis of patients with chikungunya to help direct public and clinical mitigation efforts including reducing mosquito exposures and vector control.

Cross-sectional Study (describe):

Cohort Study (describe):

Case-Control Study (describe):

Other (describe):

Environmental Assessment (describe):

Households will be offered evaluation for mosquito breeding sites and presence of larval or adult vector mosquitoes to direct plans for mitigation efforts.

Laboratory Testing (describe):

Patients with chikungunya-like illness presentign to sentinel surveillance sites and participatns of household investigations will have serum specimens collected for

clinical diagnostic testing (RT-PCR and IgM ELISA) to confirm evidence of chikungunya or dengue virus infection.

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 dengue/chikungunya case investigation form (Appendix 3) will be completed by telephone or in-person interview with the patient and/or their healthcare provider. The questionnaires used in household investigations (Appendices 1 and 2) will be completed by in-person interview with the individual.

Telephone Interview (describe):

The dengue/chikungunya case investigation form (Appendix 3) will be completed by telephone or in-person interview with the patient and/or their healthcare provider.

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

Self-administered Internet Questionnaire (describe):

Other (describe):

Medical Record Abstraction (describe):

Biological Specimen Sample

Patients with chikungunya-like illness presentign to sentinel surveillance sites and participatns of household investigations will have serum specimens collected for clinical diagnostic testing (RT-PCR and IgM ELISA) to confirm evidence of chikungunya or dengue virus infection.

Environmental Sample:

Collect mosquito specimens to determine if Aedes species mosquito density, and calculate infection rates.

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):

Mosquito-avoidance behaviors.

Clinical information/symptoms (describe):

Clinical signs/symptoms consistent with dengue or chikungunya virus infection

Contact information (describe):

Residence address and patient phone number

 Demographic information (describe):

Age and sex

 Environmental factors (describe): Exposures (describe): Medical history (describe):

Chronic medical conditions

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

Serum specimen collection date and dengue and chikungunya diagnostic test results

 Travel history (describe):

Recent travel to areas with known chikungunya transmission

 Other (describe):

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

90 days for sentinel surveillance; 4 weeks for household investigations

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

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: Dr. Tyler Sharp

Date of Certification: 06/16/2014

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

06/19/2014

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

Date/Time final GenIC received
by ICRL

Date/Time submitted to OMB

Date/Time approved