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 # 2014007 - XXX **Date** 06/12/2014

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 risk factors for chikungunya virus infections—US Virgin Islands, 2014

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

State:	US Virgin Islands
City/County (if applicable)	
Country	United States

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

Agency:	US Virgin Islands Department of Health
Name and Position Title:	Darice Plaskett, Health Commissioner

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 May 30, 2014, a total of 103,018 suspected and 4,406 laboratory-confirmed chikungunya cases had been reported from these areas. On June 6, the US Virgin Islands Department of Health identified the first locally-transmitted case of chikungunya in that territory. The case-patient had onset of acute fever and arthralgia on May 20. She is a resident of St. Thomas and denied any travel outside in the 2 weeks before her illness began. As has recently occurred in many Caribbean countries, the number of chikungunya cases in US Virgin Islands may increase rapidly. The Department of Health is requesting assistance to strengthen

surveillance and diagnostic capacity, investigate confirmed cases, assist with education of healthcare providers and the public, and provide recommendations for vector control and other mitigation efforts.

The Epi-Aid team will: 1) Assist with investigations of laboratory-confirmed cases to identify risk factors for infection and target control measures; 2) Help strengthen surveillance and diagnostic testing capacity to identify additional cases; 3) Establish routine surveillance data analysis and reports to track outbreak and direct response efforts; 4) Educate healthcare providers and the general public to recognize cases and mitigate spread; 5) Assess existing clinical capacity and needs; 6) Collect mosquito specimens to determine if Aedes albopictus is present and playing a role in transmission, calculate infection rates, and assess for insecticide resistance; and 7) Develop recommendations for vector control and other prevention efforts.

Case investigations of patients will be conducted among patients who present for medical care with a illness clinically compatible with chikungunya. Case investigations might identify additional cases with clinically compatible illness in the same household or neighborhood. Healthcare providers might be interviewed or medical records abstracted to obtain initial clinical information prior to contacting case patients. Information will be collected from cases to identify demographic or geographic risk factors for infection. Appendix 1 is a Dengue/Chikungunya Case Investigation Form, which is the form currently being used by U.S. Virgin Islands to collect clinical information on chikungunya patients. This is a standard case investigation form used for dengue and chikungunya investigations. This form might be modified in the field to add questions related to risk factors or factors deemed important following intitial investigation. Patients with fever and arthralgia/arthritis will have serum specimens collected for clinical diagnostic testing (RT-PCR and/or IgM ELISA) to confirm evidence of dengue or chikungunya virus infection. U.S Virgin Islands is collecting serum specimens as documented on the case investiation form (Appendix 1). CDC will assist with biospecimen sample collection if requested by U.S. Virgin Islands. In addition, case households will be evaluated for mosquito breeding sites and presence of larval or adult vector mosquitoes to direct plans for mitigation efforts. Additional data might be collected in the field if determined necessary for identification of risk factors and to inform prevention and control measures.

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):
- ☐ 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/chikingunya case investigation form (Appendix 1).

☐ Laboratory staff (describe):

☒ Patients (describe):

Residents of US Virgin Islands with suspected or laboratory-confirmed chikungunya virus infections

☐ 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 an illness clinically compatible with chikungunya (i.e., fever and arthralgia/arthritis). Case investigations might identify additional cases with clinically compatible illness 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):

Perform case investigations to identify demographic or geographic risk factors for infection to help direct 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):

Case households will be evaluated for mosquito breeding sites and presence of larval or adult vector mosquitoes to direct plans for mitigation efforts.

☒ Laboratory Testing (describe):

Patients with fever and arthralgia/arthritis will have serum specimens collected for clinical diagnostic testing (RT-PCR and/or IgM ELISA) to confirm evidence of dengue or chikungunya 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/chikingunya case investigation form (Appendix 1) will be completed by telephone or in-person interview with the patient and/or their healthcare provider.

☒ Telephone Interview (describe):

The dengue/chikingunya case investigation form (Appendix 1) 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 fever and arthralgia/arthritis will have serum specimens collected for clinical diagnostic testing (RT-PCR and/or IgM ELISA) to confirm evidence of dengue or chikungunya virus infection.

☒ Environmental Sample:

Collect mosquito specimens to determine if Aedes albopictus is present and playing a role in transmission, calculate infection rates, and assess for insecticide resistance.

☐ 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):

☒ 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):

☐ 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):
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

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. Marc Fischer

Date of Certification: 06/11/2014

Requested Approval Date (mm/dd/yyyy): *Instruction: Indicate the date by which approval is needed.*
06/16/2014

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	6/12/2014, 10:59AM
Date/Time final GenIC received by ICRL	6/12/2014, 5:05PM
Date/Time submitted to OMB	6/12/2014, 5:35PM
Date/Time approved	