

**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 # 2014009 - XXX

Date 7/2/2014

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 agent and risk factors for chikungunya or dengue virus infections among community service volunteers in the Dominican Republic, 2014

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

Initial Deployment

State:

FL

City/County (if applicable)

Miami

Country

USA

Second Deployment

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:

Texas Department of State Health Services

Name and Position Title:

Linda Gaul, State Epidemiologist

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 is a newly-emerging illness in the Caribbean, with the first cases officially reported in that region during December, 2013. Since the initial reporting, case counts in areas of the Caribbean, including the Dominican Republic (DR), have risen substantially, placing both resident populations and travelers at greater risk of illness. On June 20, 2014, PAHO reported 89,720 suspected cases of chikungunya in the DR. In addition, dengue, transmitted by the same vectors as chikungunya, remains a risk for both residents and travelers to the region. The Ministry of Public Health in the DR has also reported an additional 3,174 probable cases of dengue in 2014.

On 23 June 2014, CDC was notified by a US service organization about 5 illnesses suspected to be from chikungunya virus (CHIKV) infections among their staff in the DR. This service organization, headquartered in Texas, sends high school-aged volunteers originating from multiple states in the United States for cultural immersion and service projects in several countries mostly throughout Central and South America, and the Caribbean. The volunteers are accompanied by in country adult supervisory staff; it was among these staff that the suspected illnesses were reported. Volunteers and supervisory staff typically serve for either four or eight week service projects, primarily during the summer months.

Because of the ongoing chikungunya outbreak and cases of dengue in the DR, the service organization reported concern for the 147 volunteers and staff that are currently or will be serving in the DR this summer, especially because they typically stay in remote areas with local families in areas without consistent or regular vector control programs. It is not clear at this time whether initial suspected infections are dengue virus (DENV) or CHIKV infections, what factors may increase the risk for infection, if education measures to improve mosquito bite prevention are adequate, and if these individuals could translocate either DENV or CHIKV to the United States after their return.

The Texas Department of Health, where the US service organization is headquartered, is requesting assistance to conduct an investigation of these returning volunteers and staff. The service organization, the DR Ministry of Health, and the Florida Department of Health are all aware of the proposed investigation. This investigation has the following objectives:

Among volunteers and staff traveling to the Dominican Republic, the primary objectives of this investigation are to:

- Determine the incidence of recently-acquired:
 - a) CHIKV infections and consequent clinically apparent illness
 - b) Dengue virus (DENV) infections and consequent clinically apparent illness
- Conduct surveys to determine risk factors for:
 - a) CHIKV infection
 - b) DENV infection
- Recommend prevention and control measures for:
 - a) CHIKV infection
 - b) DENV infections

The investigation will comprise a self-administered questionnaire (Appendix 1), to be completed by the service organization volunteers and staff currently serving in the DR. All participants will also have one serum specimen collected (3-4 cc target) to detect evidence of recent CHIKV and DENV infection. The questionnaire and the serum sampling will be done at the terminus of the participants' service in the DR.

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):

The 147 volunteers and staff assigned to the DR by the service organization will be invited to participate. All those assigned to the DR during from June 11 to August 14, 2014 will be contacted and offered participation in the investigation, including completion of a questionnaire (Appendix 1) and diagnostic testing for chikungunya and dengue.

Healthcare staff (describe):

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.*

Eligible respondents will be identified by the service organization. An attempt to recruit participation of the entire cohort of volunteers/staff traveling to the DR this summer (2014) will be made. A volunteer/staff list with travel itinerary will be provided by the service organization. The flights carrying returning volunteers and staff back to the United States will be met at the Miami International Airport and, with the support of the DGMQ Miami Quarantine Station, questionnaires and clinical specimen collection will be completed.

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):

Service volunteers/staff will be investigated for evidence of CHIKV or DENV infection and illness. In addition, demographic, geographic, and behavioral factors associated with infection will be investigated.

Cross-sectional Study (describe):

Cohort Study (describe):

Case-Control Study (describe):

Other (describe):

Environmental Assessment (describe):

Laboratory Testing (describe):

All participants will have one serum specimen collected (3-4 cc target) to detect evidence of recent CHIKV and DENV infection. All samples will be tested by RT-PCR (dengue and chikungunya), IgM ELISA (dengue and chikungunya) and IgG ELISA (chikungunya and dengue); all IgG-positive specimens will be confirmed by plaque reduction neutralization test (PRNT). Serum specimens will be sent to the CDC Dengue Branch in San Juan, Puerto Rico, where they will be batched and tested. During the intervening period, all specimens will be stored under appropriate conditions. Chikungunya PRNTs will be performed at CDC Arboviral Diseases Branch in Fort Collins, Colorado.

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 chikungunya/dengue Case Report Form (Appendix 1) will be completed by the participant as a self-administered data collection instrument. A draft self-administered questionnaire form is provided and will be finalized and modified in the field as necessary.

Telephone Interview (describe):

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

Self-administered Internet Questionnaire (describe):

Other (describe):

Medical Record Abstraction (describe):

Biological Specimen Sample

A single blood sample (target 7 cc) will be collected from each participant for CHIKV and DENV diagnostic testing as described above.

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):
Mosquito-avoidance behaviors.
- Clinical information/symptoms (describe):
Clinical signs/symptoms consistent with DENV or CHIKV infection.
- Contact information (describe):
List of service organization volunteers and staff, with travel itineraries for test results and clinical follow up
- Demographic information (describe):
Age, sex, state of residence
- Environmental factors (describe):
Presence of screened windows, air conditioning, standing water sources around residence, etc.
- Exposures (describe):
Recall of mosquito/insect bites, recall of mosquito visualizations, etc.
- Medical history (describe):
- Risk factors (describe):
Use of mosquito bite prevention measures, outdoor activities, etc.
- Specimen/lab information (describe):
Serum samples will be collected and sent to the DVBD Dengue Branch in Puerto Rico for testing.
- Travel history (describe):
Previous travel history and immunization (specifically yellow fever) will be collected via questionnaire to aid in interpretation of test results. The service organization has provided itineraries for the current trip to the DR.
- Other (describe):

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

During the course of six weeks. Specifically, data will be collected on July 9, August 6, and August 14 at the Miami International Airport CDC DGMQ Quarantine Station.

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: Emily Jentes, PhD, MPH
 Title: Epidemiologist
 Affiliation: Division of Global Migration and Quarantine, Travelers' Health Branch

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:
Name:
Title:

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:
Date of Certification:

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

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