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 # 2015003 - XXX **Date** 12/12/2014

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 dengue virus infection— Arizona, 2014.

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

State:	Arizona
City/County (if applicable)	Yuma county
Country	USA

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

Agency:	Arizona Department of Health Services
Name and Position Title:	Ken Komatsu, 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 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).*

Dengue is a potentially fatal acute febrile illness that is transmitted by *Aedes* species mosquitoes. Dengue is endemic throughout the tropics and sub-tropics worldwide, and recent outbreaks in the United States have occurred in Florida, Hawaii, and Texas. Prior outbreaks in south Texas have occurred in association with dengue epidemics in northern Mexico. During 2008–2013, the mean number of travel-associated dengue cases reported by Arizona to ArboNET, the national arboviral surveillance system, was 4 (range: 0–12). Thus far in 2014, a total of 72 travel-associated, laboratory-positive dengue cases have been identified in Arizona, most of which occurred in Yuma and were associated with recent travel to northern Mexico, where an epidemic is ongoing. The clinical course of these patients has not yet been fully described. Although locally acquired dengue cases have not yet been identified, the number of travel-associated cases, potential under-identification of clinically apparent dengue cases, and ~75% rate of asymptomatic infection together suggest that locally acquired dengue virus (DENV) infections are likely occurring. To develop effective prevention and control measures for locally acquired infections, an investigation is needed to determine the extent to

which locally acquired infections is occurring and to identify risk factors for infection.

The Arizona Department of Health Services requests CDC assistance with an investigation in Yuma, Arizona to: 1) Identify unreported travel-associated or locally acquired dengue cases by conducting household-based cluster investigations around the homes of reported, laboratory-positive dengue cases. Household and individual questionnaires (Appendices 1 and 2) will be collected from participants, immature mosquitoes from water containers in and around the house will be collected to count mosquito larvae and mosquitoes will be collected from the home (Appendix 3), and serum specimens will be collected and tested by RT-PCR and IgM ELISA to detect current and recent DENV infection, respectively (Appendix 2); 2) Conduct entomologic surveillance for *Aedes* mosquitoes in conjunction with the cluster investigations, including testing of serum specimen collected in the household investigation for serologic evidence of recent *Aedes* mosquito bites (Appendix 2); 3) Abstract the medical records (Appendix 4) of clinically apparent, laboratory-positive dengue cases to describe their clinical course. Medical records will be abstracted by federal staff on the investigation team. Specimen collection, storage, and transport will done according to local procedures and protocols. CDC will also assist Arizona with conducting web-based and/or in-person trainings with local physicians on the clinical management of dengue.

Information collected in this investigation will be used to inform local prevention and control measures, including development of educational materials in Spanish and English for the public to prevent additional dengue cases.

This request is to obtain OMB approval for the household interviews, serum collection, and environmental sampling (Appendices 1, 2, and 3) and medical record abstraction (Appendix 4).

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-positive dengue case-patients in Arizona (Appendices 1 and 2).
- ☐ Healthcare staff (describe):
- ☐ Laboratory staff (describe):
- ☐ Patients (describe):
- ☐ Restaurant staff (describe):
- ☒ Other (describe):
  Hospital staff from whom medical records will be requested to collect the charts of laboratory-positive dengue cases so that an investigation team member can abstract it (Appendix 4).

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.*

Reported, laboratory-positive dengue case-patients will be contacted, and the nature and purpose of the investigation will be explained to them. They, other individuals living in their household, and neighbors living within a 50 meter radius of their home will be offered participation in the investigation. Neighbors will be contacted by knocking on the front door of their home.

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):

All willing household members and neighbors of reported, laboratory-positive dengue cases will be included in the investigation.

☐ Cross-sectional Study (describe):

☐ Cohort Study (describe):

☐ Case-Control Study (describe):

☐ Other (describe):

☐ Environmental Assessment (describe):

☒ Laboratory Testing (describe):

Participants' serum specimens will be tested for evidence of current or recent DENV infection, and for evidence of recently being bitten by *Aedes* species mosquitoes. Specimens sent to private diagnostic laboratories from Arizona for dengue diagnostic testing will be forwarded to CDC-Dengue Branch and tested by RT-PCR and IgM ELISA.

☐ 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):

Household and interview questionnaires will be completed through in-person interview with participants.

☐ Telephone Interview (describe):

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

☐ Self-administered Internet Questionnaire (describe):

☐ Other (describe):

☒ Medical Record Abstraction (describe):

Medical records of clinically apparent, laboratory-positive dengue cases will be abstracted to collect information to describe their clinical course.

☒ Biological Specimen Sample

Serum specimens will be collected and tested by RT-PCR and IgM ELISA to detect current and recent DENV infection.

☒ Environmental Sample:

We will count the number of mosquito larvae in water containers in and around the house and use a backpack vacuum to capture adult mosquitoes in the home (Appendix 3).

☐ 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 (e.g., use of mosquito repellent, wearing long sleeves and pants). (Appendix 2)

☒ Clinical information/symptoms (describe):

Clinical signs and symptoms of clinically apparent dengue patients (Appendix 4)

☒ Contact information (describe):

Name, phone number, and GPS coordinates will be collected from participants of the household investigations (Appendix 1)

☒ Demographic information (describe):

Age, sex, and race will be collected from participants of the household investigations (Appendices 1 and 2) and from the medical records of clinically apparent, laboratory-positive dengue cases (Appendix 4).

☐ Environmental factors (describe):

Immature mosquito specimens will be collected (Appendix 3)

☐ Exposures (describe):

☐ Medical history (describe):

☐ Risk factors (describe):

☒ Specimen/lab information (describe):

Diagnostic test results from private laboratories will be collected; serum specimens will be collected from participants of the household investigations for dengue diagnostic testing and to assess for serologic evidence of recently being bitten by *Aedes* mosquitoes.

☒ Travel history (describe):

History of travel outside of Arizona will be collected for participants of the household investigations (Appendix 2) as well as clinically-apparent, laboratory-positive dengue cases (Appendix 4).

☐ Other (describe):

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

12

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:	Jefferson Jones, MD
Title:	EIS officer
Affiliation:	CDC and Arizona Department of Health Services

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:	NCEZID/DBVD/DB
Name:	Tyler M. Sharp, Ph.D.
Title:	Acting Epidemiology 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, Tyler M. Sharp, 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:	Tyler M. Sharp, Ph.D.
Date of Certification:	12/12/14

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

12/15/14

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	12/11/2014, 7:21PM
Date/Time final GenIC received by ICRL	12/12/14, 3:00PM
Date/Time submitted to OMB	12/12/14
Date/Time approved	
