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 # 2016020 - XXX **Date** 07/22/2016

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 Mode of Transmission_Zika Virus among Utah Community Members, 2016

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

State:	Utah
City/County (if applicable)	Salt Lake City
Country	USA

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

Agency:	Utah Department of Health
Name and Position Title:	Angela Dunn, Deputy 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).*

On June 25th, 2016, a 73-year-old male died in a Salt Lake City hospital. He had returned from Mexico on June 14 and began feeling unwell on June 17. He initially sought care two days later (June 19) and was admitted on June 22. Following admission, his health rapidly declined and he died 3 days following admission with suspected dengue hemorrhagic shock syndrome. Testing performed after his death identified Zika viral RNA in a blood sample obtained during his hospital admission; the level of viremia in his blood sample, as suggested by the values obtained with the RT-PCR assay, were uncharacteristically high.

On July 1st, an adult male family contact reported developing a subjective fever and then progressed to develop a rash and conjunctivitis. The family contact had no history of travel or sexual contact with someone who traveled, but had been in contact with the index patient during his period of viremia. Testing of urine obtained 7 days after illness onset for the family contact was positive for Zika viral RNA at the Utah State Public Health Laboratory. Because the family contact did not report travel to a Zika-affected area or sexual contact with anyone who had recently traveled to a Zika-affected area, there is concern about local transmission through a potentially unidentified mode of transmission or by local mosquito-borne transmission.

The Utah Department of Health is requesting CDC's assistance to better define how the second case was infected, given his contact with the index case. CDC will assist with the following investigation objectives:

1. Assess the potential of person-to-person transmission among family contacts and health care providers
2. Evaluate the potential for environmental transmission of Zika virus through vector surveillance and a community survey
3. Assist Utah Department of Health with communication messaging
4. Develop guidelines for prevention of potential person-to-person transmission of Zika virus based on the findings of the investigation

The team will perform enhanced surveillance of community members residing within 200 meter radius of the properties of interest for evidence of recent Zika virus infection/disease. Community members will be surveyed about potential exposures and asked to provide a blood sample for Zika testing.

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):

Community members who reside within 200 meter radius of the properties of interest for evidence of recent Zika virus infection/disease

☐ 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.*

Community members who reside within 200 meter radius of the properties of interest for evidence of recent Zika virus infection/disease

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):
- ☐ Cross-sectional Study (describe):
- ☐ Cohort Study (describe):
- ☐ Case-Control Study (describe):
- ☒ Other (describe): Community Based serosurvey

☐ Environmental Assessment (describe):

☒ Laboratory Testing (describe): For those who provide blood sample

☐ 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):

Households within the 200 meter radius will be visited by investigation teams consisting of an interviewer, a phlebotomist, and a person familiar with the location, either an employee of the local health department or other government employee.

☐ Telephone Interview (describe):

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

☐ Self-administered Internet Questionnaire (describe):

☐ Other (describe):

☐ Medical Record Abstraction (describe):

☒ Biological Specimen Sample

Blood 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):

☐ Clinical information/symptoms (describe):

☒ Contact information (describe):

Name, address and DOB

☒ Demographic information (describe):

Gender, age

☐ Environmental factors (describe):

☐ Exposures (describe):

Exposure to mosquitos

☒ Medical history (describe):

Symptoms related to Zika
Plans to become pregnant and vaccination history

☐ Risk factors (describe):

☐ Specimen/lab information (describe):

☒ Travel history (describe):
Recent travel

☐ Other (describe):

8. Duration of Data Collection (number of weeks):
Community survey: 1 Week

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:	Erin Staples
Title:	Arboviral SME
Affiliation:	CDC/ DVBD/ADB

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:	OPHPR/DEO
Name:	Maleeka Glover, mglover@cdc.gov
Title:	Medical Investigations Team Lead/ CERT 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, [Maleeka Glover], 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:	Maleeka Glover
Date of Certification:	7/21/2016

Requested Approval Date (mm/dd/yyyy): *Instruction: Indicate the date by which approval is needed.*
07/22/2016

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	
