

**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 sources, modes of transmission, risk factors, and health outcomes for Zika virus infection – American Samoa, 2016

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).*

Zika virus is a mosquito-borne flavivirus that is primarily transmitted to humans by the same *Aedes* species mosquitoes that transmit dengue and chikungunya viruses. An estimated 80% of persons who are infected with Zika virus are asymptomatic. Symptomatic disease generally is mild and characterized by acute onset of fever, maculopapular rash, arthralgia, or nonpurulent conjunctivitis. However, during recent outbreaks, new modes of transmission (i.e., in utero, intrapartum, sexual, and blood transfusion), and new clinical manifestations (i.e., Guillain Barre syndrome and congenital infection resulting in fetal loss and microcephaly) have been described.

Zika virus was first identified in Uganda in 1947. Prior to 2007, only sporadic disease cases were reported from countries in Africa and Asia. In 2007, the first documented Zika virus outbreak was reported in Yap State, Federated States of Micronesia. In subsequent

years, outbreaks were identified in Southeast Asia and the Western Pacific, including French Polynesia, New Caledonia, and the Cook Islands. In 2015, local transmission of Zika virus was first identified in the Americas, with autochthonous cases in Brazil. By February 2016, local transmission had been identified in 26 countries or territories in the Americas. Recently, Zika virus disease cases have been identified in Tonga and Samoa.

In 2014 and 2015, American Samoa experienced outbreaks due to chikungunya and dengue viruses. In December 2015 and January 2016, the American Samoa Department of Health reported an increase in patients with rash illness from various health centers throughout the island. Since then, additional cases with rash, conjunctivitis, and joint pain have been noted. On January 28, the New Zealand Ministry of Health reported a case of laboratory-confirmed Zika virus disease in a recent traveler to American Samoa. Although Zika virus disease cases have not been confirmed in American Samoa, these events suggest that local transmission might be occurring and further investigation and response is needed. The magnitude of Zika virus transmission in American Samoa as well as risk factors and negative health outcomes for a Zika virus disease outbreak need to be understood in order to recommend appropriate control measures.

The American Samoa Department of Public Health has requested CDC's assistance to respond to this potential outbreak. The results of this investigation will be used to identify prevention and control measures for Zika virus infection and its sequelae.

Objectives of the investigation include:

1. Review and summarize syndromic surveillance data for rash illness and facilitate laboratory testing for evidence of Zika virus infections.
2. Provide technical assistance to describe the epidemiology of suspected and confirmed Zika virus disease cases to direct prevention and control efforts.
3. To assist with education and increasing awareness of healthcare providers and the general public regarding Zika virus infection and additional aspects of outbreak response management.

This GenIC requests approval for urgent data collection necessary for prevention and control of Zika virus and negative health outcomes associated with infection to address objectives 1-2, including,

1. Zika Virus Disease Case Investigation Form (Appendix 1).

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):

Health department staff to which suspected Zika virus cases are reported.

Healthcare staff (describe):

Healthcare and laboratory staff who contribute information to the case report.

Laboratory staff (describe):

Healthcare and laboratory staff who contribute information to the case report.

Patients (describe):

Persons who exhibit symptoms consistent with Zika virus infection or its sequelae who reported for care at local hospitals or health centers

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.*

Persons who report to local hospitals and health centers with symptoms consistent with Zika virus infection or its sequelae. Symptom, risk factor and clinical information for suspected cases are reported by the health center or hospital to the local health department.

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):

This investigation will confirm and characterize the outbreak of Zika virus infection in American Samoa.

Cross-sectional Study (describe):

Cohort Study (describe):

Case-Control Study (describe):

Other (describe):

Environmental Assessment (describe):

Laboratory Testing (describe):

Specimens from suspected Zika virus cases will be obtained and tested for the suspected infectious pathogens at CDC. Specimens will be tested at CDC for presence of or antibodies against suspected infectious pathogens (e.g., Zika, dengue, chikungunya viruses).

Specimen collection, storage, and transport will be performed according to local procedures and protocols.

Other (describe):

Other ancillary response efforts to provide data leading to outbreak control will also be

carried out.

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):

Information will be obtained from medical records and face-to-face interviews (Appendix 1)

Telephone Interview (describe):

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

Self-administered Internet Questionnaire (describe):

Other (describe):

Medical Record Abstraction (describe):

Public health personnel from CDC and the American Samoa Department of Health will perform medical chart reviews about suspected cases (Appendix 1)

Biological Specimen Sample

Any specimens from suspected Zika virus cases that were previously collected and still available at the hospital or commercial or public health laboratories will be obtained and similarly tested for the suspected infectious pathogens at CDC. When previously collected specimens are unavailable to confirm cases, serum will be collected from suspected cases using standard techniques at the time of interview. Specimens will be tested at CDC for presence of or antibodies against suspected infectious pathogens (e.g., Zika, dengue, chikungunya viruses).

Specimen collection, storage, and transport will be performed according to local procedures and protocols.

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):

Travel history, vaccination history

Clinical information/symptoms (describe):

Pregnancy status, microcephaly, high risk clinical procedures (blood/organ transplant).
Illness information (fever, rash, etc.)

Contact information (describe):

- Demographic information (describe):
State of residence, age, sex
- Environmental factors (describe):
- Exposures (describe):
- Medical history (describe):
Symptoms
- Risk factors (describe):
Vaccination history, transfusion, transplant, breastfeeding
- Specimen/lab information (describe):
Type and date specimens collected
- Travel history (describe):
Countries visited and dates
- Other (describe):

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

4

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: Marc Fischer

Title: Chief, Surveillance and Epidemiology Activity

Affiliation: NCEZID/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: NCEZID/DVBD/ADB

Name: Marc Fischer

Title: Chief, Surveillance and Epidemiology Activity

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, Marc Fischer, 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:

Marc Fischer

Date of Certification:

02/09/16

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

2/13/2016

E-mail the completed form to the Information Collection Request Liaison (ICRL) or EIS program ICRL designee.

EI Information Collection Request Liaison:

Danice Eaton, PhD, MPH
EIS Program Staff Epidemiologist
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