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 # 2016011 - XXX **Date** 02/16/2015

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 — Puerto Rico, 2016

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

State:	Puerto Rico
City/County (if applicable)	
Country	U.S. Territories

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

Agency:	Puerto Rico Department of Health
Name and Position Title:	Brenda Rivera-Garcia, Territorial 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).*

Zika virus is a mosquito-borne flavivirus transmitted by *Aedes* species mosquitoes. Around 1 in 5 people infected with Zika virus become symptomatic, and the most common symptoms include fever, rash, joint pain, and conjunctivitis. The illness is usually mild and self-limited with symptoms lasting for several days to a week. No vaccine is available and treatment is supportive. However, during recent outbreaks, new modes of transmission (i.e., in utero, intrapartum, sexual, and blood transfusion), and new serious clinical manifestations (i.e., Guillain-Barre syndrome and congenital infection resulting in fetal loss and microcephaly) have been described.

Prior to 2015, Zika virus outbreaks had been identified in Africa, Southeast Asia, and the Pacific Islands. In May 2015, the World Health Organization reported an outbreak of Zika in Brazil, with an estimated 440,000–1,300,000 suspected cases of Zika virus disease having occurred through the end of 2015. Locally-acquired cases of Zika virus disease have since been identified in 27

countries and territories in the Americas. In December 2015, the first locally-acquired case of Zika virus disease was identified in the U.S. territory of Puerto Rico.

As of February 5, 2016, 27 cases of Zika virus disease have been laboratory-confirmed in Puerto Rico, all except one are considered locally-acquired infections. The full spectrum of potential modes of transmission and health consequences of Zika virus infection are not well understood. Because infection could potentially lead to severe health outcomes (e.g. microcephaly in infants and Guillain-Barre syndrome), there is an urgent public health need to better understand the epidemiology of and risk factors for Zika virus infection in affected areas. There also is concern for the potential for Zika virus to be transmitted from blood donors to transfusion recipients in Puerto Rico. Several interventions are under consideration for immediate implementation in order to mitigate the risk of Zika virus transmission by blood transfusion in Puerto Rico. Characterization of the local collections and blood use is imperative to inform feasibility of public health interventions, including outsourcing of blood components to Puerto Rico from areas of the U.S. not affected by Zika virus.

The Puerto Rico Department of Health (PR DOH) has requested CDC's assistance to respond to the Zika virus outbreak in Puerto Rico. The results will be used to identify and inform prevention and control measures for Zika virus infection and its sequelae.

The objectives of the investigation include the following:

1. Provide technical assistance to the PR DOH to improve surveillance for Zika-like illness and potential negative health outcomes, particularly in pregnant women;
2. Describe the epidemiology of suspected and confirmed Zika virus disease cases and potential negative health outcomes to direct prevention and control efforts.
3. Characterize local blood collections and blood product usage in Puerto Rico to better assist partners with identifying safe sources of blood products during the Zika outbreak to prevent infection from transfusions;
4. Provide guidance on public messaging and additional aspects of outbreak response.

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 the objectives, including,

1. Zika virus disease case investigation form (Appendix 1)
2. Urgent assessment and use of blood collection in Puerto Rico in response to the Zika virus outbreak: survey questionnaire (Appendix 2)

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):

PRDOH staff will complete the case investigation form for suspected Zika virus cases that are reported to PRDOH. (Appendix 1)

☒ Healthcare staff (describe):

Case investigation form: Healthcare and laboratory staff who contribute information to the case report. (Appendix 1)
Blood collection assessment: Surveys will be distributed to the administrators of local blood collection facilities in Puerto Rico and medical directors of all hospitals in Puerto Rico. (Appendix 2)

☒ Laboratory staff (describe):

Case investigation form: Healthcare and laboratory staff who contribute information to the case report. (Appendix 1)
Blood collection assessment: A survey will collect information regarding blood product pathogen screening which may require input from laboratory personnel regarding screening processes. (Appendix 2)

☒ Patients (describe):

Case investigation form: Persons who exhibit symptoms consistent with Zika virus infection or its sequelae reported to PR DOH. (Appendix 1)

☐ 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.*

Case investigation form: Patients with illness consistent with Zika virus infection or its sequelae reported to PR DOH. (Appendix 1)

Blood collection assessment: All 9 blood collection organizations and all 63 hospitals in Puerto Rico will be asked to complete the survey. (Appendix 2)

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):

Case investigation form: This investigation will confirm and characterize the outbreak of Zika virus infection and potential negative health outcomes in Puerto Rico. (Appendix 1)

Blood collection assessment: Information obtained from blood collection organizations and hospitals will be used to characterize local blood collection methods and blood product utilization which will be used to estimate the volume of blood products needed for transfusions to recipients at high risk for severe outcomes of Zika virus infection (e.g., pregnant women, neonates) and the volume which could be subjected to pathogen reduction technology. This information will be used to inform the identification of safe blood products to prevent transmission of Zika virus infection through transfusions. (Appendix 2)

☐ Cross-sectional Study (describe):

☐ Cohort Study (describe):

☐ Case-Control Study (describe):

☐ Other (describe):

☐ Environmental Assessment (describe):

☒ Laboratory Testing (describe):

Case Investigations: 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):

Case investigations: Information will be obtained from face-to-face interviews with patients (Appendix 1)

☒ Telephone Interview (describe):

Case investigations: Information will be obtained from telephone interviews with patients (Appendix 1)

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

Blood collection assessment: A self-administered questionnaire will be distributed to the blood collection agencies and hospitals. (Appendix 2)

☐ Self-administered Internet Questionnaire (describe):

☐ Other (describe):

☒ Medical Record Abstraction (describe):

Case Investigations: Public health personnel from CDC and the Puerto Rico Department of Health will perform medical chart reviews about suspected cases (Appendix 1)

☒ Biological Specimen Sample

Case Investigations: 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):
Case investigations: Travel history, vaccination history (Appendix 1)

☒ Clinical information/symptoms (describe):
Case investigations: Pregnancy status, microcephaly, high risk clinical procedures (blood/organ transplant). Illness information (fever, rash, etc.) (Appendix 1)

☒ Contact information (describe):
Blood collection assessment: Name, address, and telephone number for those completing the survey as well as facility name, address and identifier. No patient contact information will be collected. (Appendix 2)

☒ Demographic information (describe):
Case investigations: Basic demographics (Appendix 1)

☐ Environmental factors (describe):

☐ Exposures (describe):

☒ Medical history (describe):
Case investigations: Symptoms (Appendix 1)

☒ Risk factors (describe):
Case investigations: Vaccination history, transfusion, transplant, breastfeeding (Appendix 1)

☒ Specimen/lab information (describe):
Case investigations: Type and date specimens collected (Appendix 1)

☒ Travel history (describe):
Case investigations: Countries visited and dates (Appendix 1)

☒ Other (describe):
Blood collection assessment: Donor blood collection methods and product types, characterization of blood product distribution methods, number of blood products transfused to Zika high risk groups, blood pathogens tested, basic demographic information of blood recipient patients, cost of blood product collection and use. (Appendix 2)

8. Duration of Data Collection (number of weeks):
12 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

CDC Investigation Lead: *Instruction: Indicate the name, title, and affiliation of the person who will serve as the CDC lead for this investigation.*

Name:	Sridhar Basavaraju
Title:	Medical Officer, CDR, USPHS
Affiliation:	OID/NCEZID/DHQP/Office of Blood, Organ, and Other Tissue Safety

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/DHQP/PRB
Name:	Amber Vasquez
Title:	Epidemic Intelligence Service Officer

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:	Amber Vasquez
Date of Certification:	2/16/2016

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

2/19/2016

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	