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 # 0920 - 1011 **Date** 01/13/2016

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 agent, source, mode of transmission, and risk factors for an outbreak of Guillain-Barré Syndrome, Bahia – Brazil, 2016

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

State:	Bahia
City/County (if applicable)	Salvador
Country	Brazil

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

Agency:	Brazil Ministry of Health
Name and Position Title:	Giovanini Evelim Coelho, Chief of Arbovirus Surveillance, Secretariat de Vigilancia em Saud, Brazil MOH

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).*

In early 2015, several clusters of Guillain-Barré syndrome (GBS) were being reported in Brazil with most of the cases occurring in Pernambuco and Bahia. During the same time frame, Brazil identified its first cases of Zika virus. By spring 2015, Brazil had documented several hundred laboratory-confirmed cases of Zika virus, demonstrating that the virus had rapidly spread throughout the country, with the highest number of cases occurring in two particular states - Pernambuco and Bahia, the same region as the GBS cases. Zika virus infection in humans is believed to be largely asymptomatic or mildly symptomatic with nonspecific symptoms of fever, rash, arthralgia, myalgia, and headaches. Confounding the picture was the fact that Brazil was simultaneously experiencing a reemergence of chikungunya virus and an increase in cases of dengue. Since 2013, there have been five reported clusters of GBS in the Western Pacific,

hypothesized to be associated with emerging arboviruses, including two clusters in French Polynesia thought to be associated with Zika virus, one outbreak in New Caledonia attributed to chikungunya virus, and another outbreak of GBS in Fiji that occurred during a large dengue epidemic. This apparent co-emergence of Zika virus and GBS cases in Brazil represents the sixth such report in two years. Preliminary investigations by the Brazil Ministry of Health (MOH) have been inconclusive, leading the MOH to request assistance from CDC to further evaluate the possible association of GBS with Zika virus and/or a combination of Zika virus along with other co-circulating arboviruses in susceptible individuals. Demonstration of such an association would demonstrate an increased importance for vector control programs to protect people from mosquito-borne diseases. Objectives of the investigation include:
1.) Develop a line list of GBS patients in Bahia.
2.) Obtain specimens previously collected from GBS patients at time of acute illness, if available, which will be sent to CDC for serologic testing.
3.) Perform a case-control investigation to determine rates of arboviral infections and other exposures among GBS cases and controls through a combination of interviews (Appendices 1a and 1b), medical chart reviews (Appendices 2a and 2b), and collection of biological samples (e.g. serum / whole blood, urine) from cases and controls for etiologic testing at CDC.

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):

Face-to-face interviews with cases and matched controls regarding exposure history. Controls will be matched on age and location of residence. Interviews will be conducted in either English or Portuguese as appropriate (Appendices 1a and 1b).

☐ 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.*

Interviews will be conducted as part of the planned case-control investigation. Cases will be selected from residents of Bahia with a diagnosis of GBS meeting levels 1-3 of diagnostic certainty for the Brighton Collaboration criteria case definition for GBS since January 1, 2015. At least two controls will be pair-matched to each case by age group. Controls will be randomly selected from households within a one kilometer radius of case-patients' household of residence. Project personnel will use GoogleEarth to locate the household of each case patient based on available surveillance data. A one kilometer radius will be drawn, and a random number generator will be used to calculate a random direction (i.e. between 0 and 360 degrees) from the case-patient household and also a random distance (i.e. between 0 and 1000 meters) from the case-patient household. This process will be repeated until an apparent household is selected. If there is no age-matched control available the same day in the first household, the team will spin a one-sided object and proceed to the closest household in which the one-sided object points, and the process will be repeated until an appropriate control is identified.

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):

Cases and controls will undergo in-person interviews to ascertain information about activities, antecedent signs and symptoms of illness, and exposures in the two months prior to onset of neurologic illness for cases and the same time period for their age-matched controls (Appendices 1a and 1b).

Serum, whole blood, and urine samples will be collected at the time of interview and tested for suspected infectious pathogens. Specimen collection, storage, and transport will be done according to local procedures and protocols.

Following written consent, additional medical information will be obtained through medical chart review using a standardized chart abstraction form (Appendices 2a and 2b).

☐ Other (describe):

☐ Environmental Assessment (describe):

☒ Laboratory Testing (describe):

1) Any serologic specimens from GBS cases in Bahia that were previously collected within two months of GBS symptom onset (or same time frame for controls) and still available at the hospital or commercial or public health laboratories will also be obtained and similarly tested for the suspected infectious pathogens at CDC.
2) As part of the case-control study, serum and urine from cases and controls will be collected using standard techniques at the time of interview. Specimens will be tested at

CDC for antibodies against suspected infectious pathogens (e.g. Zika virus, dengue, chikungunya). Specimen collection, storage, and transport will be done according to local procedures and protocols.

☐ 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):

A symptom and exposure questionnaire (Appendices 1a and 1b) will be administered to cases and controls through face-to-face interviews.

☐ 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 the CDC and Brazil MOH investigation team will perform medical chart reviews to gather objective information about cases and controls after obtaining written consent (Appendices 2a and 2b).

☐ Biological Specimen 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):

Antecedent signs and symptoms prior to neurologic illness; clinical course; relevant laboratory data obtained during period of interest; other potentially useful clinical results such as imaging or electrodiagnostic testing

☒ Contact information (describe):

Address, phone numbers, alternate contacts

☒ Demographic information (describe):

Basic demographics

☐ Environmental factors (describe):

☒ Exposures (describe):
Exposures to animals, types of food, source of drinking water, mosquito bites, handling

☒ Medical history (describe):
History of significant underlying medical comorbidities, with particular emphasis on prior history of neurologic illness

☒ Risk factors (describe):
Query cases and controls on several potential risk factors for exposure to arboviruses and other select pathogens; query about nutritional status

☒ Specimen/lab information (describe):
Specimen type, date collected, volume collected

☒ Travel history (describe):
History of travel outside of home village / town in 2 months prior to illness onset

☐ Other (describe):

8. Duration of Data Collection (number of weeks):
3 weeks initially, potentially up to 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:	Jim Sejvar
Title:	Medical Officer
Affiliation:	NCEZID/DHCPP/PPHO

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/DHCPP/PPHO
Name:	Ashley Styczynski
EIS Off Title:	EIS 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, Ashley Styczynski, 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:	Ashley Styczynski
Date of Certification:	1/13/2016

Requested Approval Date (mm/dd/yyyy): *Instruction: Indicate the date by which approval is needed.*
1/17/2016

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	
