

**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 # 2016015 - XXX Date 07 April 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 Guillain-Barré Syndrome in the setting of Zika virus transmission — Colombia, 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).*

The first locally acquired case of Zika virus disease was identified in Colombia in October 2015. As of March 12, 2016, a total of 52,724 cases of Zika virus disease were reported in Colombia. Thirty-four of 37 geographic areas have reported laboratory confirmed cases. To date, 10,319 cases with symptoms of Zika virus disease have been reported in Colombia, of which 995 (10%) were confirmed by RT-PCR testing. The highest cases and incidence rates are in the reporting areas of Norte de Santander, Barranquilla, and Huila. Furthermore, multiple clusters of Guillain-Barré syndrome (GBS) were also being recognized in Norte de Santander and Barranquilla – areas of the country also experiencing some of the highest rates of reporting of Zika-like illness.

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. More recently, Brazil had experienced the new introduction and emergence of Zika virus, during which the virus quickly spread to affect numerous areas of the country. Shortly after the recognition of Zika virus in Brazil, increased reports of GBS began to emerge, with the GBS increases being noted in areas of the country most heavily associated with Zika virus disease. A recently conducted case control investigation into Zika virus and GBS in the northeastern state of Bahia, demonstrated a tight geo-spatial clustering of GBS cases and an incidence of GBS nearly 10 times the baseline rate. Of note, GBS cases were substantially more likely than age- and residence-matched controls to report conjunctivitis and rash illness, suggestive of Zika virus illness among cases. The probable outbreak of GBS cases in Brazil in the setting of a large Zika virus outbreak would represent the sixth such report in 2 years. Since that time, increases in reports of GBS following the introduction of Zika virus have been reported from 12 countries, including Colombia.

The Colombian Ministry of Health and Instituto Nacional de Salud have requested 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 Colombia.

The objectives of this investigation will be to:

1. Develop a line list of patients with suspected GBS in Colombia.
2. Obtain specimens previously collected from GBS patients at time of acute illness, if available, to test for Zika virus and other arboviruses
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), and medical chart reviews (Appendices 2a and 2b)
4. Collect clinical specimens (serum / whole blood, and urine) from GBS cases and controls to identify potential infectious etiologic agents.

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 group and location of residence. Interviews will be conducted in Spanish (Appendices 1a and 1b).

- Healthcare staff (describe):
- Laboratory staff (describe):
- Patients (describe):

Face-to-face interviews with cases regarding exposure history, symptomatology, and past medical history. Interviews will be conducted in Spanish (Appendices 1a and 1b).
- Restaurant staff (describe):
- Other (describe):

Public health personnel to perform medical chart reviews for case patients. (Appendices 2a and 2b)

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 Colombian residents who received a physician-reported diagnosis of GBS or a hospital discharge code corresponding with GBS (ICD-9 357.0 / ICD-10 G67.0) from October 2015 to present. GBS patient medical records will be reviewed, to determine if they meet standard case definition criteria for GBS (meeting levels 1-3 of diagnostic certainty for the Brighton Collaboration criteria case definition for GBS) since 01 October, 2015.

Controls will be selected from within the same neighborhood as the case-patient's household of residence. A coin will be flipped to determine direction (heads = right; tails = left). A random number generator (1-20) will be used to determine the number of properties to travel in the given direction before locating a control. If a selected location is clearly uninhabited, interviewers will continue traveling in the same direction until an occupied household is located. If there is no age-matched control available in the first household, the team will continue in the same direction until an age-matched control can be ascertained. For selection of a second control, the random number generator (1-20) will be again used to determine the number of properties to travel, continuing in the same direction as before, until an available control is located. If all households that are immediately adjacent to the randomly selected household are visited and an age-matched control is not identified, another randomly selected household will be visited to find a control.

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) As part of the case control investigation, serum / whole blood and urine 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.

2) Any serologic specimens from GBS cases that were previously collected within two months of GBS symptom onset 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.

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):

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 Colombia INS investigation team will perform medical chart reviews to gather objective information about cases and controls (if undergoing medical evaluation during the period of interest) after obtaining written consent (Appendices 2a and 2b).

Biological Specimen Sample

Serum / whole blood 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.

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):

4 – 6 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:

Title:

Affiliation:

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:

Name:

EIS Off
Title:

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, James J. Sejvar, 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:

Date of Certification:

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

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
 EWB/DSEPD/CDC
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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