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 # 2016005 - 007 **Date** 12/06/2015

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 risk of exposure for human-to-human spread of rabies to contact of case patient following mongoose-associated human rabies case, Puerto Rico, 2015.

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

State:	Puerto Rico
City/County (if applicable)	
Country	USA

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, Puerto Rico 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).*

On December 1, 2015, CDC was contacted by the Puerto Rico Department of Health regarding a possible case of human rabies in a 54 year old man. The patient initially presented to the ER on 11/30/15 with fevers, shortness of breath, confusion, anxiety, hydrophobia/dysphagia, and paresthesias since 11/23/15. He was noted to be responsive but confused on exam with no evidence of paralysis or respiratory failure. His family reported a history of a mongoose bite approximately one month prior for which he did not receive medical care. He was noted to have otherwise been healthy except for hyperlipidemia and depression related to unemployment. The hospital contacted the Puerto Rico Department of Health about the concern for rabies.

As the patient was being transported from the ER to the ICU on the evening of 12/1/15, he went into cardiac arrest and was unable to be resuscitated. Direct fluorescent antibody testing of brain tissue collected at autopsy performed by the Puerto Rico Public Health Laboratory was positive indicating a diagnosis of rabies. This is the first known case of human rabies on Puerto Rico from mongoose bite exposure.

In Puerto Rico, the majority of post-exposure prophylaxis (PEP) for rabies is supplied by the Department of Health, and the supply is currently limited because of fiscal constraints. Given the supply limitation of PEP and the community's anxiety about possible exposures, Puerto Rico Department of Health has requested assistance with conducting contract tracing and standardized risk assessments for persons with possible exposures to the patient to ensure only those individuals with actual exposures receive PEP.

The case-patient's infectious period is generally considered as two weeks prior to the onset of first symptoms (11/9/15-12/1/15). Given the extended period of time during which the patient was contagious, an extensive case investigation and risk assessment of possible contacts is needed.

The objectives of the investigation include:

1) Identify community and healthcare contacts of the case patient during potential infectious period (11/9/15 – 12/1/15)
2) Perform risk assessments for rabies virus exposure of contacts to determine need for PEP
3) Develop healthcare community educational tools on occupational exposure to rabies

This request is to obtain OMB for the risk assessments (Appendices 1-2). Appendix 1 assesses risk factors for rabies exposure among non-clinical patient contacts (e.g., household and co-workers). Appendix 2 assesses risk factors for rabies exposure among clinical contacts (healthcare workers). To address objective 3, CDC will provide subject matter expertise review of a fact sheet on occupational exposure to rabies developed by the Puerto Rico Department of Health.

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 had contact with the case patient during 11/9/15-12/1/15

☒ Healthcare staff (describe):

Healthcare workers who provided direct care to the case patient during 11/9/15-12/1/15 including his most recent hospitalization

☐ 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.*

Appendix 1: Respondents will be family and community contacts who might have had direct contact with the patient since 11/9/15. These contacts will be identified through discussions with family members of the patient.

Appendix 2: Respondents will be healthcare workers who might have had direct contact with the case patient. These contacts will be identified by hospital administration who will provide a list of hospital personnel who directly cared for the patient. Persons identified as contacts will complete either the community (Appendix 1) or healthcare worker (Appendix 2) risk factor assessment.

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):

To conduct contact tracing and standardized risk assessments for persons with possible exposures to the case patient to ascertain which individuals require post-exposure prophylaxis

☐ Cross-sectional Study (describe):

☐ Cohort Study (describe):

☐ Case-Control Study (describe):

☐ Other (describe):

☐ Environmental Assessment (describe):

☐ Laboratory Testing (describe):

☐ 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):

We will interview patient community contacts (Appendix 1) and healthcare worker contacts (Appendix 2) in person, if available.

☒ Telephone Interview (describe):

If contacts of the case patient are not available for in-person interviews, they will be contacted by telephone for administering a risk assessment questionnaire (Appendices 1 and 2).

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

☐ Self-administered Internet Questionnaire (describe):

Other (describe):

☐ Medical Record Abstraction (describe):

☐ 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):

☐ Contact information (describe):

☒ Demographic information (describe):

Name, contact information including addresses and telephone numbers

☐ Environmental factors (describe):

☒ Exposures (describe):

Nature and timing of contacts with case patient

☐ Medical history (describe):

☒ Risk factors (describe):

Same as exposures

☐ Specimen/lab information (describe):

☐ Travel history (describe):

☐ Other (describe):

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

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:	Ashley Styczynski
Title:	EIS Officer
Affiliation:	NCEZID/DHCPP/PRB

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/PRB
Name:	Brett Petersen
Title:	Medical 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, Brett Petersen, 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:	Brett Petersen
Date of Certification:	12/04/2015

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

12/07/2015

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
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