

**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]*

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).*

Early September 2015, a four year old girl died from a rabies like illness in Gonaives, Haiti. According to a preliminary investigation conducted late September, the child was bitten on the stomach by an aggressive dog, owned by the household (dog died about a week after the bite incident). Prior to her death, she exhibited clinical symptoms of rabies: agitation, paralysis on the right side, and hydrophobia. She was not taken to the hospital and the case was not officially reported through Haiti's National Surveillance System (NSS). Furthermore, a preliminary investigation by the Ministry of Agriculture identified at least six dogs in this rural community with rabies-like illness and a Ministry of Health investigation identified an additional 5 bite victims that had not sought treatment nor reported the rabies exposure to a healthcare professional.

This is extremely concerning, given the case fatality of rabies is almost 100% if bite victims do not seek care for post-exposure prophylaxis (PEP) treatment as soon as possible. Furthermore, the breakdown of reporting to the NSS may adversely impact PEP and canine rabies vaccination procurement, leading to a potential shortage when another outbreak occurs. To develop effective prevention and control measures, an investigation is needed to identify additional cases and risk factors for rabies infection and care-seeking behavior for those who are bitten.

The goal of this investigation are to:

- 1) Identify additional bite victims and refer for immediate treatment at a medical center
- 2) Assess knowledge of rabies and barriers to care if bitten
- 3) Estimate the rabies vaccination rates among pet owners
- 4) Assess public health officials knowledge of treatment for rabies, availability of PEP at their treatment center, and if and how they are reporting these cases to the National Surveillance System

CDC will provide technical expertise on the two surveys. Ministerial staff will conduct all surveys during the investigation. The first survey will be given to community members (Appendix 1). The second survey will be administered to public health officials, with slight variation to the questions depending on the type of official [Appendices 2a-b (medical providers), Appendices 3a-b (rabies officials), Appendices 4a-b (public health officials)]. These surveys will be administered by Haiti Ministry of Health or Agriculture staff in French.

This request is to obtain OMB for the surveys (Appendices 1-4).

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):

Adult community members ≥ 18 years old will be interviewed about rabies knowledge, health care seeking behavior, and dog ownership.

Healthcare staff (describe):

Among adult medical providers, rabies officials, and public health officials ≥ 18 years old will be interviewed about their position (Appendices 2a-2b, 3a-3b, 4a-4b), how their position relates to dog bite investigations (Appendices 3a-3b) and reporting of rabies (Appendices

2a2b, 3a-3b, 4a-4b) 4), barriers associated to reporting (Appendices 2-2b, 3a-3bm 4a-4b), rabies knowledge and treatment (Appendices 2a-2b,3a-3b,4a-4b), availability of PEP (Appendices 2a-2b,3a-3b,4a-4b), and recommendations for surveillance improvements (Appendices 2a-2b, 3a-3b,4a-4b).

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.*

Adult community members residing where the outbreak has happened are identified and selected. Health care workers, administrators, and sanitation officers working in institutions that provide care to bite victims are also selected. The exact methodology will be determined in collaboration with the Ministry of Health during the investigation.

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 describe the epidemiology of the outbreak, and assess treatment seeking behaviors and response capabilities in order to to make recommendations for controlling the outbreak and preventing cases of Haiti.

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 adult community members ≥ 18 years old and health care officials (medical providers, rabies officials, and public health officials).

Telephone Interview (describe):

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):

Personal protective equipment usage (Appendices 2a-2b and 3a-3b).

Clinical information/symptoms (describe):

Contact information (describe):

Demographic information (describe):

Age, gender, location of area they live, education, and people living in their households (Appendices 1a -1b, 2a-2b, 3a-3b,4a-4b)

Environmental factors (describe):

Exposures (describe):

Owning and vaccinating household pets (dogs and cats) and contact with rabid animals (Appendices 1a-1b and 3a-3b)

Medical history (describe):

Risk factors (describe):

Owning and vaccinating household pets (dogs and cats), contact with rabid animals, knowledge about rabies, and health care seeking behavior after a bite (Appendices 1a-1b and 2a-2b)

Specimen/lab information (describe): Travel history (describe): Other (describe):

Among adult medical providers, rabies officials, and public health officials ≥ 18 years old will be interviewed about their position (Appendices 2a-2b,3a-3b,4a-4b), how their position relates to dog bite investigations (Appendices 3a-3b) and reporting of rabies (Appendices 2a-2b, 3a-3b, 4a-4b) 4), barriers associated to reporting (Appendices 2-2b, 3a-3b, 4a-4b), rabies knowledge and treatment (Appendices 2a-2b,3a-3b,4a-4b), availability of PEP (Appendices 2a-2b,3a-3b,4a-4b), and recommendations for surveillance improvements (Appendices 2a-2b, 3a-3b,4a-4b).

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: Ryan Wallace

Title: Veterinary Medical 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: Ryan Wallace

Title: Veterinary 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, Ryan Wallace, 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:

Ryan Wallace

Date of Certification:

10/29/2015

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

11/2/2015

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
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