

**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 # 2015006 - 012

Date 02/12/2015

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 mode of transmission and risk factors for potential *Burkholderia pseudomallei* exposures among non-human primates, and persons employed at or inspecting a primate research center — Louisiana, 2015

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

State:

Louisiana

City/County (if applicable)

Covington

Country

USA

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

Agency:

Louisiana Department of Health and Hospitals Office of Public Health

Name and Position Title:

Raoult Ratard, State 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).*

Melioidosis is an infectious disease caused by the gram-negative bacterium *Burkholderia pseudomallei*, which is a select agent. Melioidosis is extremely rare in the U.S., and most cases are associated with travel to endemic regions, such as Southeast Asia and Australia. On 15 December 2014, CDC was contacted about potential cases of melioidosis in two non-human primates (NHP) at a national primate research center in Louisiana. The center houses approximately 5,000 NHPs within multiple enclosed pens with outdoor runs. The facility employs about 300 staff.

Testing performed at the CDC Zoonoses and Select Agent Laboratory on December 19th confirmed both NHPs were infected with *B. pseudomallei*. Further genotyping revealed that the NHPs were infected with the laboratory reference strain 1026b, which was used in the northern research part of the campus located 1 mile away from the primate colony. During December 19-23, 2014, an investigation was conducted at the research center by CDC/Division of Select Agents and Toxins (DSAT) and USDA Select Agents Program. The federal inspectors were accompanied by personnel from the Louisiana Department of Health and Human Services Office of Public Health, the Louisiana Department of Agriculture and Forestry, and the university that runs the research center. On January 23, a member of the USDA inspection team developed an illness with melioidosis as a differential diagnosis. The patient's serum antibody titer was consistent with potentially recent or distant exposure to *B. pseudomallei*. Through the patient reported distant travel to an endemic country, given the patient's recent visit to the research center, concerns were raised for possible exposure during the investigation by CDC and USDA.

The Louisiana Department of Health and Hospitals Office of Public Health requested CDC assistance to:

1. Provide technical subject matter expertise in support of DSAT investigation of laboratory biosafety lapses that potentially led to infections in NHPs;
2. Review historical risk assessments of animal and laboratory workers at and inspection of the primate research center;
3. Conduct additional risk assessments, if needed, of potentially exposed personnel as investigation continues, including center employees and facility inspectors;
4. Provide technical subject matter expertise to guide sampling strategy to assess potential *B. pseudomallei* exposure to center employees, facility inspectors, and the surrounding community and to guide recommendations for prevention and control.

Additionally, the CDC laboratory will perform serology and soil testing on samples collected from persons as well as the environment. Specimen collection, storage, and transport will be conducted according to local procedures and protocols.

This GenIC seeks approval for one data collection to identify potential risk factors and exposures among laboratory and animal workers, and inspectors of the research center. Investigators will use Appendix 1 (Risk Assessment).

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):

Healthcare staff (describe):

Laboratory staff (describe):
Laboratory staff will be assessed for potential lab exposures using the “risk assessment for primate research center employees and inspectors” tool (Appendix 1)

Patients (describe):

Restaurant staff (describe):

Other (describe):
Animal workers and other research center staff , and facility inspectors will be assessed for potential exposures using the “risk assessment for primate research center employees and inspectors” tool (Appendix 1)

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.*

The research center will assist with the identification of animal and laboratory workers who have worked in the area where the two infected non-human primates (NHP) were housed, the laboratories where work with *B. pseudomallei* was performed, and other locations where the investigation determines potential exposure may have occurred will be 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):

Other (describe):

Environmental Assessment (describe):

Laboratory Testing (describe):
Serum specimens will be collected from staff or state/local inspectors identified to be at risk for *B. pseudomallei* infection. Soil samples will be collected from the environment surrounding the facility. Testing of both will be performed by CDC laboratory.

Other (describe):
Risk assessment of animal and laboratory workers and state/local inspectors (Appendix 1)

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):

Staff and state/local inspectors will be interviewed about travel history, risk factors, and involvement in the area where the two infected non-human primates were housed (Appendix 1).

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):

Clinical information/symptoms (describe):

Contact information (describe):

Demographic information (describe):

Environmental factors (describe):

Exposures (describe):

Staff and state/local inspectors involvement in the area where the two infected non-human primates were housed

Medical history (describe):

Risk factors (describe):

Staff and state/local inspectors will be interviewed to identify any predisposing risk factors to

meliodosis (Appendix 1)

Specimen/lab information (describe):

Travel history (describe):

Staff and state/local inspectors will be interviewed for prior travel history in countries known to be endemic for melioidosis (Appendix 1)

Other (describe):

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

4 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: David Blaney, MD, MPH, FACPM / Leisha Nolen, MD, PhD

Title: D. Blaney (EIS Supervisor, Medical Epidemiologist) – L. Nolen (EIS Officer)

Affiliation: CDC, Bacterial Special Pathogens Branch

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: NCZEID/DHCP/BSPB

Name: Henry Walke, MD, MPH / Sean Shadomy, DVM, MPH, DACVPM

Title: H. Walke (Branch Chief) – S. Shadomy (Acting Epidemiology Team Lead)

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: Henry Walke, MD

Date of Certification: 02/12/2015

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

02/13/2015

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
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