Burden Memo for the Generic Clearance of Emergency Epidemic Investigation Data Collections (0920-1011)

GenIC No.:	2015003-XXX
EPI AID No. (if applicable):	
Requesting entity (e.g., jurisdiction):	Arizona Department of Health Services
Title of Investigation:	Undetermined risk factors for dengue virus infection— Arizona, 2014.
Purpose of Investigation: (Use as much space as necessary)	Dengue is a potentially fatal acute febrile illness that is transmitted by *Aedes* species mosquitoes. Dengue is endemic throughout the tropics and sub-tropics worldwide, and recent outbreaks in the United States have occurred in Florida, Hawaii, and Texas. Prior outbreaks in south Texas have occurred in association with dengue epidemics in northern Mexico. During 2008–2013, the mean number of travel-associated dengue cases reported by Arizona to ArboNET, the national arboviral surveillance system, was 4 (range: 0–12). Thus far in 2014, a total of 72 travel-associated, laboratory-positive dengue cases have been identified in Arizona, most of which occurred in Yuma and were associated with recent travel to northern Mexico, where an epidemic is ongoing. The clinical course of these patients has not yet been fully described. Although locally acquired dengue cases have not yet been identified, the number of travel-associated cases, potential under-identification of clinically apparent dengue cases, and ~75% rate of asymptomatic infection together suggest that locally acquired dengue virus (DENV) infections are likely occurring. To develop effective prevention and control measures for locally acquired infections, an investigation is needed to determine the extent to which locally acquired infections is occurring and to identify risk factors for infection. The Arizona Department of Health Services requested CDC assistance with an investigation in Yuma, Arizona to: 1) Identify unreported travel-associated or locally acquired dengue cases by conducting household-based cluster investigations around the homes of reported, laboratory-positive dengue cases. Household and individual questionnaires (Appendices 1 and 2) will be collected from participants, immature mosquitoes from water containers in and around the house will be collected to count mosquito larvae and mosquitoes will be collected from the home (Appendix 3), and serum specimens will be collected and tested by RT-PCR and IgM ELISA to detect current and recent DENV infection, respectively (Appendix 2); 2) Conduct entomologic surveillance for *Aedes* mosquitoes in conjunction with the cluster investigations, including testing of serum specimen collected in the household investigation for serologic evidence of recent *Aedes* mosquito bites (Appendix 2); 3) Abstract the medical records (Appendix 4) of clinically apparent, laboratory-positive dengue cases to describe their clinical course. Medical records will be abstracted by federal staff on the investigation team. Specimen collection, storage, and transport will done according to local procedures and protocols. CDC also assisted Arizona with conducting web-based and/or in-person trainings with local physicians on the clinical management of dengue. Information collected in this investigation will be used to inform local prevention and control measures, including development of educational materials in Spanish and English for the public to prevent additional dengue cases.
Duration of Data Collection:	12 weeks
Date Began:	12/15/2014
Date Ended:	3/13/2015
Lead Investigator	
Name:	Jefferson Jones, MD MPH
CIO/Division/Branch:	CDC and Arizona Department of Health Services

Complete the following for <u>each</u> instrument used during the investigation.

Data Collection Instrument 1

Name of Data Collection Instrument: Household questionnaire

Type of Respondent

☒ General public ☐ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff
☐ Other (describe):

Data Collection Methods (check all that apply)

☒ Epidemiologic Study (indicate which type(s) below)
- ☒ Descriptive Study (describe): Describe household-level risk factors for *Aedes spp*. mosquito bites
- ☐ Cross-sectional Study (describe):
- ☐ Cohort Study (describe):
- ☐ Case-Control Study (describe):
- ☐ Other (describe):

☐ Environmental Assessment (describe):
☐ Laboratory Testing (describe):
☐ Other (describe):

Data Collection Mode (check all that apply)

☐ Survey Mode (indicate which mode(s) below):
- ☒ Face-to-face Interview (describe): Administered face-to-face at household; recruited by knocking on all doors within 50 meters of lab-confirmed dengue case patient.
- ☐ 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):

Response Rate (if applicable)

Total No. Responded (A):	115
Total No. Sampled/Eligible to Respond (B):	170
Response Rate (A/B):	68%

Data Collection Instrument 2

Name of Data Collection Instrument: Individual questionnaire

Type of Respondent

☒ General public ☐ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff
☐ Other (describe):

Data Collection Methods (check all that apply)

☒ Epidemiologic Study (indicate which type(s) below)
- ☒ Descriptive Study (describe): Describe individual-level risk factors for *Aedes spp*. mosquito

bites; recruited by knocking on all doors within 50 meters of lab-confirmed dengue case patient.

- ☐ Cross-sectional Study (describe):
- ☐ Cohort Study (describe):
- ☐ Case-Control Study (describe):
- ☐ Other (describe):
- ☐ Environmental Assessment (describe):
- ☐ Laboratory Testing (describe):
- ☐ Other (describe):

Data Collection Mode (check all that apply)

- ☐ Survey Mode (indicate which mode(s) below):
  - ☒ Face-to-face Interview (describe): Administered face-to-face at household
  - ☐ Telephone Interview (describe):
  - ☐ Self-administered Paper-and-Pencil Questionnaire (describe):
  - ☐ Self-administered Internet Questionnaire (describe):
  - ☐ Other (describe):
- ☐ Medical Record Abstraction (describe):
- ☒ Biological Specimen Sample: Blood sample
- ☐ Environmental Sample
- ☐ Other (describe):

Response Rate (if applicable)

Total No. Responded (A):	194
Total No. Sampled/Eligible to Respond (B):	Not recorded at individual level
Response Rate (A/B):	Unknown

Data Collection Instrument 3

Name of Data Collection Instrument: Immature mosquito survey form.

Type of Respondent

☒ General public ☐ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff

☐ Other (describe):

Data Collection Methods (check all that apply)

- ☒ Epidemiologic Study (indicate which type(s) below)
  - ☒ Descriptive Study (describe): Describe level of containers, containers with water, containers with *Aedes spp*. larvae in households.
  - ☐ Cross-sectional Study (describe):
  - ☐ Cohort Study (describe):
  - ☐ Case-Control Study (describe):
  - ☐ Other (describe):
- ☐ Environmental Assessment (describe):
- ☐ Laboratory Testing (describe):
- ☐ Other (describe):

Data Collection Mode (check all that apply)

- ☐ Survey Mode (indicate which mode(s) below):
  - ☐ Face-to-face Interview (describe):
  - ☐ 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 — Team recorded data from observations of household yards. Also used tools to look for larvae in water-containing containers.
- ☐ Other (describe):

Response Rate (if applicable)

Total No. Responded (A):	115
Total No. Sampled/Eligible to Respond (B):	170
Response Rate (A/B):	68%

Data Collection Instrument 4

Name of Data Collection Instrument: Informed consent form

Type of Respondent

☒ General public ☐ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff

☐ Other (describe):

Data Collection Methods (check all that apply)

- ☐ 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):
- ☐ Other (describe): NONE

Data Collection Mode (check all that apply)

- ☐ Survey Mode (indicate which mode(s) below):
  - ☐ Face-to-face Interview (describe):
  - ☐ 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): Signed form, answered questions if person had any

Response Rate (if applicable)

Total No. Responded (A):	194
Total No. Sampled/Eligible to Respond (B):	Not recorded at individual level
Response Rate (A/B):	Unknown

Data Collection Instrument 5

Name of Data Collection Instrument: Dengue case investigation form

Type of Respondent

☐ General public ☐ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff

☒ Other (describe): Health department personnel filled using medical records

Data Collection Methods (check all that apply)

- ☒ Epidemiologic Study (indicate which type(s) below)
  - ☒ Descriptive Study (describe): Describe clinical data of dengue outbreak
  - ☐ Cross-sectional Study (describe):
  - ☐ Cohort Study (describe):
  - ☐ Case-Control Study (describe):
  - ☐ Other (describe):
- ☐ Environmental Assessment (describe):
- ☐ Laboratory Testing (describe):
- ☐ Other (describe):

Data Collection Mode (check all that apply)

- ☐ Survey Mode (indicate which mode(s) below):
  - ☐ Face-to-face Interview (describe):
  - ☐ Telephone Interview (describe):
  - ☐ Self-administered Paper-and-Pencil Questionnaire (describe):
  - ☐ Self-administered Internet Questionnaire (describe):
  - ☐ Other (describe):
- ☒ Medical Record Abstraction (describe): Used standardized medical abstraction form on medical records requested from known medical facilities.
- ☐ Biological Specimen Sample
- ☐ Environmental Sample
- ☐ Other (describe):

Response Rate (if applicable)

Total No. Responded (A):	68
Total No. Sampled/Eligible to Respond (B):	68
Response Rate (A/B):	100

Complete the following burden table. Each data collection instrument should be included as a separate row.

Burden Table (insert rows for additional respondent types if needed)

Data Collection Instrument Name	Type of Respondent	Data Collection Mode	No. Respondents (A)	No. Responses per Respondent (B)	Burden per Response in Minutes (C)	Total Burden in Hours (A x B x C)/60*
Household questionnaire	Public	In-person interview	115	1	20	38
Individual questionnaire	Public	In-person interview	194	1	20	65
Immature mosquito survey form.	Public	Field investigation	113	1	30	57
Informed consent/assent form	Public	In-person interview	194	1	5	16
Dengue case investigation form	Medical record staff	Chart abstraction	68	1	20	23

Return completed form and a blank copy of each final data collection instrument within 5 business days of data collection completion to the EEI Information Collection Request Liaison, Danice Eaton (dhe0@cdc.gov).

EEI Information Collection Request Liaison:
Danice Eaton, PhD, MPH
EIS Program Staff Epidemiologist
Epidemiology Workforce Branch
Division of Scientific Education and Professional Development
Centers for Disease Control and Prevention
2400 Century Center, MS E-92
Office: 404.498.6389
Deaton@cdc.gov

Burden Memo for the Generic Clearance of Emergency Epidemic Investigation Data Collections (0920-1011)

GenIC No.:	2015004-XXX
EPI AID No. (if applicable):	2015-005
Requesting entity (e.g., jurisdiction):	Kansas Department of Health and Environment
Title of Investigation:	Undetermined risk factors for mucormycosis among immunocompromised patients — Kansas, 2014
Purpose of Investigation: (Use as much space as necessary)	Mucormycosis is a serious, often fatal infection, caused by a group of angioinvasive molds. These infections most commonly affect the rhinocerebral area and occur typically in persons with marked immunosuppression. On December 1, 2014, the Centers for Disease Control and Prevention (CDC) was notified by the Kansas Department of Health and Environment (KDHE) of a cluster of mucormycosis infections among patients in a bone marrow transplant (BMT) unit in Hospital A in Kansas. The hospital reported four rhinocerebral mucormycosis infections and one pulmonary mucormycosis infection which had occurred in the prior two months. A possible source of these infections was thought to be construction on the BMT unit, which occurred from May to October of 2014. However, because several of the cases had presented after the construction was completed, Hospital A was concerned that there may be additional relevant exposures in this cluster that might still be unidentified. Hospital A states that they typically identify one case of rhinocerebral mucormycosis in this patient population per year. Hospital A and the KDHE requested CDC assistance to: 1) conduct case-finding; 2) determine if significantly higher number of infections has occurred as compared with historical baseline; 3) characterize epidemiological and clinical aspects of case-patients, including exposures of interest; 4) conduct an epidemiological study to evaluate potential association between exposures and cases; and 5) provide recommendations for preventative measures and remediation.
Duration of Data Collection:	18 days
Date Began:	12/29/2014
Date Ended:	1/15/2014
Lead Investigator	
Name:	Tiffany Walker
CIO/Division/Branch:	NCEZID/DFWED/Mycotic Diseases

Complete the following for each instrument used during the investigation.

Data Collection Instrument 1

Name of Data Collection Instrument: Mucormycosis_Infection Prevention and Control Questions

Type of Respondent

☐ General public ☒ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff

Other (describe):

Data Collection Methods (check all that apply)

☐ 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):
- ☒ Other (describe): Hypothesis generation

Data Collection Mode (check all that apply)

- ☒ Survey Mode (indicate which mode(s) below):
  - ☒ Face-to-face Interview (describe): Questions were administered via a face-to-face unstructured interview.
  - ☐ 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):

Response Rate (if applicable)

Total No. Responded (A):	29
Total No. Sampled/Eligible to Respond (B):	29
Response Rate (A/B):	100%

Data Collection Instrument 2

Name of Data Collection Instrument: Mucormycosis_Medical Record Abstraction Form

Type of Respondent

☐ General public ☐ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff

☒ Other (describe): Public Health professionals (CDC employees, state employees, and trainees)

Data Collection Methods (check all that apply)

- ☐ Epidemiologic Study (indicate which type(s) below)
  - ☐ Descriptive Study (describe):
  - ☐ Cross-sectional Study (describe):
  - ☐ Cohort Study (describe):
  - ☒ Case-Control Study (describe): Evaluate risk factors associated with rhinocerebral mucormycosis among patients (cases and controls) with hematological malignancies admitted to Unit 41 and Unit 42 of Hospital A from May 23-December 1, 2014
  - ☐ Other (describe):
- ☐ Environmental Assessment (describe):
- ☐ Laboratory Testing (describe):
- ☐ Other (describe):

Data Collection Mode (check all that apply)

- ☐ Survey Mode (indicate which mode(s) below):

- ☐ Face-to-face Interview (describe):
- ☐ Telephone Interview (describe):
- ☐ Self-administered Paper-and-Pencil Questionnaire (describe):
- ☐ Self-administered Internet Questionnaire (describe):
- ☐ Other (describe):
- X☐ Medical Record Abstraction (describe): Used abstraction tool to obtain demographic, risk factor and outcome data from the electronic medical record
- ☐ Biological Specimen Sample
- ☐ Environmental Sample
- ☐ Other (describe):

Response Rate (if applicable)

Total No. Responded (A):	3
Total No. Sampled/Eligible to Respond (B):	3
Response Rate (A/B):	100%

Data Collection Instrument 3

Name of Data Collection Instrument:

Type of Respondent

☐ General public ☐ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff

☐ Other (describe):

Data Collection Methods (check all that apply)

- ☐ 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):
- ☐ Other (describe):

Data Collection Mode (check all that apply)

- ☐ Survey Mode (indicate which mode(s) below):
  - ☐ Face-to-face Interview (describe):
  - ☐ 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):

Response Rate (if applicable)

Total No. Responded (A):

Response Rate (A/B):

(Additional Data Collection Instrument sections may be added if necessary.)

Complete the following burden table. Each data collection instrument should be included as a separate row.

Burden Table (insert rows for additional respondent types if needed)

Data Collection Instrument Name	Type of Respondent	No. Respondents (A)	No. Responses per Respondent (B)	Burden per Response in Minutes (C)	Total Burden in Hours (A x B x C)/60*
Appendix 1: Infection Prevention and Control Questions for Investigation of Mucormycosis Outbreak in BMT Unit Undergoing Construction	Hospital staff	29	1	20	10
Appendix 2: Investigation of Mucormycosis Disease among Bone Marrow Transplant Patients	State pubic health staff; medical student	3	4	90	16

Return completed form and a blank copy of each final data collection instrument within 5 business days of data collection completion to the EEI Information Collection Request Liaison, Danice Eaton (dhe0@cdc.gov).

EEI Information Collection Request Liaison:

Danice Eaton, PhD, MPH
EIS Program Staff Epidemiologist
Epidemiology Workforce Branch
Division of Scientific Education and Professional Development
Centers for Disease Control and Prevention
2400 Century Center, MS E-92
Office: 404.498.6389
Deaton@cdc.gov

Burden Memo for the Generic Clearance of Emergency Epidemic Investigation Data Collections (0920-1011)

GenIC No.:	2015005-XXX
EPI AID No. (if applicable):	2015-007
Requesting entity (e.g., jurisdiction):	Mozambique National Institute of Health
Title of Investigation:	Undetermined risk factors for severe illness and death among funeral attendees, Mozambique, 2014
Purpose of Investigation: (Use as much space as necessary)	On January 12th, 2015, an outbreak of severe illness and fatalities was reported among people who attended a funeral on January 9th, 2015 in Tete Province, Mozambique. Seventy-three deaths and 177 cases were reported by the Ministry of Health. The illness affected men, women, and children of different ages, with the youngest case occurring in a 2 year old child. Initial field investigation by the National Institute of Health in Mozambique suggested that the illness resulted from consumption of a traditional beverage, and that the illness is most likely due to a chemical toxin. Because of a potential environmental etiologic agent, the Mozambique Ministry of Health requested the assistance of the National Center for Environmental Health/Agency for Toxic Substances and Disease Registry in investigating the cause of illnesses and fatalities associated with attendance at the funeral event. The objectives of this investigation were to assist the Mozambique Ministry of Health in the following: 1) Identify the cause of the outbreak; 2) Confirm route of exposure; 3) Determine the risk factors for illness and death; 4) Determine if testing of biologic samples is useful, and if so, determine for which chemical agents to test (Division of Laboratory Sciences). The investigation began with a descriptive study of affected funeral attendees to identify potential risk factors and exposures of interest. The characteristics of the persons affected were described. Questionnaires were administered in-person to cases to evaluate for clinical disease. CDC is also assisting with a toxicological investigation to include testing of previously collected (by Mozambique National Institute of Health) de-identified biological samples from case patients for potential etiologies as needed. CDC investigators will not have access to personally identifiable laboratory data, nor will they have access to any identifying keys.
Duration of Data Collection:	
Date Began:	02/06/2015
Date Ended:	02/08/2015
Lead Investigator	
Name:	Amelia Kasper
CIO/Division/Branch:	NCEH/DEHHE/Health Studies Branch

Complete the following for each instrument used during the investigation.

Data Collection Instrument 1

Name of Data Collection Instrument: Tainted Beverage_Questionnaire

Type of Respondent

☒ General public ☐ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff

☐ Other (describe):

Data Collection Methods (check all that apply)

☒ Epidemiologic Study (indicate which type(s) below)

- ☒ Descriptive Study (describe): Questionnaire-based inquiry of ongoing symptoms of disease
- ☐ Cross-sectional Study (describe):
- ☐ Cohort Study (describe):
- ☐ Case-Control Study (describe):
- ☐ Other (describe):

☐ Environmental Assessment (describe):

☐ Laboratory Testing (describe):

☐ Other (describe):

Data Collection Mode (check all that apply)

☒ Survey Mode (indicate which mode(s) below):

- ☒ Face-to-face Interview (describe): Visits to 3 neighborhoods to interview people with documented histories of neurological symptoms during the outbreak.
- ☐ 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):

Response Rate (if applicable)

Total No. Responded (A):	17
Total No. Sampled/Eligible to Respond (B):	17
Response Rate (A/B):	100

Data Collection Instrument 2

Name of Data Collection Instrument: Tainted Beverage_Medical Record Abstraction

Type of Respondent

☐ General public ☐ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff

☒ Other (describe): Medical records only

Data Collection Methods (check all that apply)

☒ Epidemiologic Study (indicate which type(s) below)

- ☒ Descriptive Study (describe): Collected data to describe patient population, disease course
- ☐ Cross-sectional Study (describe):
- ☐ Cohort Study (describe):
- ☐ Case-Control Study (describe):
- ☐ Other (describe):

☐ Environmental Assessment (describe):

☐ Laboratory Testing (describe):

☐ Other (describe):

Data Collection Mode (check all that apply)

- ☐ Survey Mode (indicate which mode(s) below):
  - ☐ Face-to-face Interview (describe):
  - ☐ Telephone Interview (describe):
  - ☐ Self-administered Paper-and-Pencil Questionnaire (describe):
  - ☐ Self-administered Internet Questionnaire (describe):
  - ☐ Other (describe):
- ☒ Medical Record Abstraction (describe): Vital signs, physical examination, clinical narrative, laboratory data
- ☐ Biological Specimen Sample
- ☐ Environmental Sample
- ☐ Other (describe):

Response Rate (if applicable)

Total No. Responded (A):	65
Total No. Sampled/Eligible to Respond (B):	65
Response Rate (A/B):	100

Data Collection Instrument 3

Name of Data Collection Instrument:

Type of Respondent

☐ General public ☐ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff

☐ Other (describe):

Data Collection Methods (check all that apply)

- ☐ 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):
- ☐ Other (describe):

Data Collection Mode (check all that apply)

- ☐ Survey Mode (indicate which mode(s) below):
  - ☐ Face-to-face Interview (describe):
  - ☐ 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):

Response Rate (if applicable)

Total No. Responded (A):

Total No. Sampled/Eligible to Respond (B):

Response Rate (A/B):

(Additional Data Collection Instrument sections may be added if necessary.)

Complete the following burden table. Each data collection instrument should be included as a separate row.

Burden Table (insert rows for additional respondent types if needed)

Data Collection Instrument Name	Type of Respondent	No. Respondents (A)	No. Responses per Respondent (B)	Burden per Response in Minutes (C)	Total Burden in Hours (A x B x C)/60*
Tainted Beverage_Questionnaire	General public	17	1	20	6
Tainted Beverage_Medical Record Abstraction	Medical records only	4	17	30	34

Return completed form and a blank copy of each final data collection instrument within 5 business days of data collection completion to the EEI Information Collection Request Liaison, Danice Eaton (dhe0@cdc.gov).

EEI Information Collection Request Liaison:
Danice Eaton, PhD, MPH
EIS Program Staff Epidemiologist
Epidemiology Workforce Branch
Division of Scientific Education and Professional Development
Centers for Disease Control and Prevention
2400 Century Center, MS E-92
Office: 404.498.6389
Deaton@cdc.gov

Burden Memo for the Generic Clearance of Emergency Epidemic Investigation Data Collections (0920-1011)

GenIC No.:	2015006-XXX
EPI AID No. (if applicable):	Epi-Aid 2015-012
Requesting entity (e.g., jurisdiction):	Louisiana Department of Health and Hospitals Office of Public Health
Title of Investigation:	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
Purpose of Investigation: (Use as much space as necessary)	On 15 December 2014, CDC was contacted about potential cases of melioidosis in two non-human primates (NHP) housed in a primate research center. The center houses approximately 5000 NHPs within multiple enclosed pens with outdoor field cages or runs. The facility employs about 300 staff. Melioidosis is an infectious disease caused by the gram-negative bacterium *Burkholderia pseudomallei*. It is extremely rare in the United States, and most cases are associated with travel to endemic regions, such as Southeast Asia and Australia. Testing performed at the CDC Zoonoses and Select Agent Laboratory (ZSAL) for both NHPs was positive for *B. pseudomallei* on 18 December 2014 by *Burkholderia spp*. LRN real-time PCR and was confirmed by the LRN algorithm for *B. pseudomallei* on 19 December 2014. Further genotyping by ZSAL, including MLST and MLVA, revealed both NHPs were infected with the reference strain 1026b, the reference strain used in a research facility separated from the primate colony by approximately one mile. An initial investigation was conducted by CDC Division of Select Agents and Toxins (DSAT) and USDA Select Agents Program staff from 19-23 January 2015. On 23 January, a member of the USDA inspection team developed an illness that included melioidosis in the differential diagnosis. She presented for medical treatment on 31 January in Tennessee and again at Emory hospital on 5 February, 2015 and was hospitalized. A serum specimen obtained during the second clinical visit was tested using Indirect Hemagglutination Assay for antibodies to *B. pseudomallei* and the titer was 1:160, indicating potentially recent or distant exposure to the organism. Detailed travel history revealed distant travel and exposure to soil in a country endemic for *B. pseudomallei*; however given the patient's recent visit to the primate research center concerns were raised for possible exposure during the investigation by CDC and USDA. The CDC Bacterial Special Pathogens Branch (BSPB) epidemiology team was deployed to Covington LA on February 9th 2015. The main goals included: 1. Identify other primates exposed to *Bp* 2. Investigate the route of exposure that caused the primates to become infected with *Bp* 3. Evaluate the risk of exposure to Tulane employees 4. Assist other agencies in evaluating environmental contamination
Duration of Data Collection:	
Date Began:	February 9th 2015
Date Ended:	March 30th 2015
Lead Investigator	
Name:	Leisha Nolen
CIO/Division/Branch:	OID/NCEZID/BSPB

Complete the following for <u>each</u> instrument used during the investigation.

Data Collection Instrument 1

Name of Data Collection Instrument: Risk Assessment Questionnaire

Type of Respondent

☐ General public X Healthcare staff X Laboratory staff ☐ Patients ☐ Restaurant staff
☐ Other (describe): Veterinary clinic workers and those accessing research area

Data Collection Methods (check all that apply)

☐ 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):
X Other (describe): Risk assessment questionnaire

Data Collection Mode (check all that apply)

☐ Survey Mode (indicate which mode(s) below):
- ☐ Face-to-face Interview (describe):
- ☐ Telephone Interview (describe):
- XSelf-administered Paper-and-Pencil Questionnaire (describe): One page questionnaire that asked about laboratory exposures, PPE use, predisposing health conditions
- ☐ Self-administered Internet Questionnaire (describe):
- ☐ Other (describe):

☐ Medical Record Abstraction (describe):
☐ Biological Specimen Sample
☐ Environmental Sample
☐ Other (describe):

Response Rate (if applicable)

Total No. Responded (A): 276
Total No. Sampled/Eligible to Respond (B): 300
Response Rate (A/B): 92%

Data Collection Instrument 2

Name of Data Collection Instrument: Exposure history

Type of Respondent

☐ General public ☐ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff
☐ Other (describe):

Data Collection Methods (check all that apply)

☐ 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):	
X Laboratory Testing (describe):	Blood samples were collected from individuals at risk of Bp exposure. Demographic information and information regarding previous risk behaviors were collected.
☐ Other (describe):	

Data Collection Mode (check all that apply)

X Survey Mode (indicate which mode(s) below):	
XFace-to-face Interview (describe):	Staff members were asked questions prior to blood donation
☐ Telephone Interview (describe):	
☐ Self-administered Paper-and-Pencil Questionnaire (describe):	
☐ Self-administered Internet Questionnaire (describe):	
☐ Other (describe):	
☐ Medical Record Abstraction (describe):	
XBiological Specimen Sample	Blood samples were collected by LA DHH staff members
☐ Environmental Sample	
☐ Other (describe):	

Response Rate (if applicable)

Total No. Responded (A):	89
Total No. Sampled/Eligible to Respond (B):	120
Response Rate (A/B):	74%

Complete the following burden table. Each data collection instrument should be included as a separate row.

Burden Table (insert rows for additional respondent types if needed)

Data Collection Instrument Name	Type of Respondent	No. Respondents (A)	No. Responses per Respondent (B)	Burden per Response in Minutes (C)	Total Burden in Hours (A x B x C)/60*
Risk Assessment Questionnaire	Staff	276	1	5	1380
Exposure history	Staff	89	1	10	890

Return completed form and a blank copy of each final data collection instrument within 5 business days of data collection completion to the EEI Information Collection Request Liaison, Danice Eaton (dhe0@cdc.gov).

EEI Information Collection Request Liaison:
Danice Eaton, PhD, MPH
EIS Program Staff Epidemiologist
Epidemiology Workforce Branch
Division of Scientific Education and Professional Development
Centers for Disease Control and Prevention
2400 Century Center, MS E-92
Office: 404.498.6389
Deaton@cdc.gov