

**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

CLEARANCE 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: | American Samoa |
| 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: | American Samoa Department of Health |
| Name and Position Title: | Motusu Tuileama Nua, Director of Health |

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. At a minimum, please provide the following information: 1) background necessary to understand the importance of the outbreak or event; 2) justification of the need for an investigation, including a description of any data already available or data gaps that exist; 3) justification as to why this issue requires an urgent response; and 3) an explanation of how the information collected will be used to inform prevention and control measures. Use as much space as necessary (suggested length: 250-500 words).*

On May 20, 2014, CDC received an inquiry from the American Samoa Department of Health related to an ongoing diarrheal disease outbreak for which preliminary lab results indicate a possible mixed etiology, including *Shigella* and *Entamoeba histolytica*. To date, there have been 161 cases of diarrheal disease with 14 hospital admissions since May 2, 2014 on the island of Tutuila, American Samoa. No common exposures have been identified among case-patients; however, drinking water infrastructure is lacking with regards to meeting regulatory requirements and therefore, a waterborne source is suspected. The outbreak is ongoing and this investigation will be conducted to determine the etiology and source of the outbreak so that prevention and control measures can be implemented.

Objectives of this investigation will be:

1. Assist American Samoa DOH by determining the magnitude of and characterizing the diarrheal disease outbreak through active case-finding and systematic data collection.
2. Perform laboratory testing on clinical specimens for diarrheal pathogens.
3. Conduct an environmental investigation as indicated by epidemiologic findings to characterize case-patient exposures.

The initial investigation will likely entail active case-finding, creation of a line list of cases, and interviews of case-patients as well as review of medical charts. As informed by the epidemiologic investigation, a case-control study, clinical, and environmental laboratory investigations may also be pursued.

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):

Controls for a possible case-control study or respondents to a community survey if needed

Healthcare staff (describe):

Laboratory staff (describe):

Patients (describe):

Persons who meet the as yet to be determined case definition for diarrheal disease

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.*

Respondents will be determined by a case definition and will be identified through hospital and clinic records, emergency department visits, and laboratory reports.

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):

Describe the demographics, clinical presentation, and exposures among case-patients with diarrheal disease.

Cross-sectional Study (describe):

Cohort Study (describe):

Case-Control Study (describe):

If hypothesis-generating interviews indicate a possible risk factor for disease, a case-control study may be conducted to test the hypothesis.

Other (describe):

Environmental Assessment (describe):

Water testing and description/inspection of water infrastructure may be conducted as indicated by the epidemiologic investigation.

Laboratory Testing (describe):

Stool specimens will be tested for stool pathogens. Sera may also be tested as indicated based

on epidemiologic and laboratory findings.

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):

Case-patients may be interviewed in person to obtain data on demographics, clinical presentation, and exposures using an interview questionnaire (Attachment 2) that will be modified in the field based on the needs of this investigation.

Telephone Interview (describe):

Case-patients may be interviewed by phone to obtain data on demographics, clinical presentation, and exposures using an interview questionnaire (Attachment 2) that will be modified in the field based on the needs of this investigation.

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

Self-administered Internet Questionnaire (describe):

Other (describe):

Medical Record Abstraction (describe):

If case-patients sought medical care, their medical records will be examined using a chart abstraction form (Attachment 1) that will be modified in the field based on the needs of this investigation..

Biological Specimen Sample

Stool specimens will be tested for stool pathogens. Sera may also be tested as indicated based on epidemiologic and laboratory findings.

Environmental Sample:

Water samples may be collected and tested for stool pathogens as indicated by the epidemiologic investigation.

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):

Symptoms of diarrheal disease, timing, diagnostic testing, treatment

Contact information (describe):

- Demographic information (describe):
Age, gender, race and ethnicity, area of residence
- Environmental factors (describe):
- Exposures (describe):
Food, water, household contacts
- Medical history (describe):
Co-morbid conditions
- Risk factors (describe):
- Specimen/lab information (describe):
Stool and blood specimens. If requested, the CDC team will assist the territorial health department with the collection of clinical specimens to determine the etiological agent for this outbreak,
- Travel history (describe):
History of travel off-island
- Other (describe):

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

3

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: Jennifer Cope, MD, MPH
 Title: Medical Epidemiologist
 Affiliation: Waterborne Disease Prevention Branch, DFWED, NCEZID

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/DFWED/WDPB
 Name: Jennifer Cope, MD, MPH
 Title: Medical Epidemiologist

Contact Information: *Provide complete contact information. Check box for preferred method(s) of contact during the OMB approval process.*

| | |
|---------------------------------------------------|--------------|
| <input checked="" type="checkbox"/> Office phone: | 404-718-4878 |
| <input type="checkbox"/> Home phone: | |
| <input checked="" type="checkbox"/> Cell/Mobile: | 404-368-9877 |
| <input checked="" type="checkbox"/> E-mail: | Bjt9@cdc.gov |
| <input type="checkbox"/> Other: | |

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:

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), Danice Eaton.

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 received by ICRL | <input type="text"/> |
| Date/Time submitted to OMB | <input type="text"/> |
| Date/Time approved | <input type="text"/> |