

**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 # [2016022] - [046]

Date [8/5/2016]

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 source, mode of transmission, and risk factors for Hepatitis A virus (HAV) transmission – Hawaii, 2016

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

State:	Hawaii
City/County (if applicable)	Honolulu
Country	USA

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

Agency:	Hawaii Department of Health
Name and Position Title:	Sarah Park, State Epidemiologist, Chief, Disease Outbreak Control Division

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).*

The Hawaii Department of Health (DOH) began investigating a hepatitis A virus (HAV) cluster on the island of Oahu in June 2016. This virus is typically found in the stool of infected person is usually spread by ingesting contaminated food or water or contact with someone who is ill. Currently over 100 cases have been identified and cases have been found on 4 of the Hawaiian islands (the most affected being Oahu), and one case in a tourist who lives in Texas. Specimens sent to CDC Division of Viral Hepatitis (DVH) laboratory, confirm that cases are infected with the identical strain of hepatitis A virus, a viral strain that is has not been previously identified in the CDC's Division of Viral Hepatitis' surveillance database. A common source of exposure among ill persons has not been identified, though a food item distributed to restaurants is the leading hypothesis. The current outbreak is the largest HAV outbreak in the Hawaii, a popular tourist state, in the last 20 years. The longer the outbreak continues, the more likely secondary cases will emerge.

The Hawaii DOH has requested assistance from CDC to identify a source of the outbreak and stop further transmission of the virus. The objectives of this investigation will be to:

1. Provide epidemiological support to better elucidate the possible implication of restaurants and/or food items in the continued transmission of the virus by conducting a case-control study to obtain more definitive epidemiological evidence to identify implicated food items and eating establishments, related analyses and line list management
2. Provide guidance to help facilitate the state's efforts in product traceback of implicated food items
3. Review case data to better understand the potential health impacts suffered by infected persons

To address the objectives, this GenIC requests approval for urgent data collection necessary to conduct a case-control study in order to identify the source of illnesses and control the ongoing Hepatitis A outbreak, including,

1. Hepatitis A case questionnaire (Appendix 1)
2. Hepatitis A control questionnaire (Appendix 2)

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):

Phone or face-to-face interviews with cases and controls regarding exposure history. Interviews will be conducted in English.

Healthcare staff (describe):

Laboratory staff (describe):

Patients (describe):

Phone or face-to-face interviews with cases regarding exposure history, symptomatology and past medical history.

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.*

Interviews will be conducted as part of a proposed case-control investigation. Cases will be selected from Hawaii residents who received a diagnosis of HAV infection from June 2016 to

present.

Controls will be selected from two groups: 1) non-infected (i.e. healthy) restaurant dining companions of cases by using patron contact information obtained from implicated restaurants, or online food ordering websites, and 2) case's neighborhoods through using telephone number lists of residences within a half mile radius of each case residence. The telephone lists would be randomized, and then persons would be contacted in the order they appeared on the randomized list. The controls would be matched to cases based on age.

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):

Cases and controls will undergo telephone or in-person interviews to ascertain information about activities, antecedent signs and symptoms of illness, and exposures in the 50 days prior to onset of illness for cases and the same time period for their age-matched controls (Appendices 1 and 2).

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):

A symptom and exposure questionnaire will be administered to cases (Appendix 1) and controls (Appendix 2) through face-to-face interviews.

Telephone Interview (describe):

A symptom and exposure questionnaire will be administered to cases (Appendix 1) and controls (Appendix 2) through telephone interviews.

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):

Eating at certain restaurants.

Clinical information/symptoms (describe):

Antecedent signs and symptoms prior to illness; clinical course; relevant laboratory data obtained during period of interest

Contact information (describe):

Address, phone numbers, alternate contacts

Demographic information (describe):

Basic demographics

Environmental factors (describe):

Exposures (describe):

Exposures to different types of food, source of drinking water

Medical history (describe):

Risk factors (describe):

Query cases and controls on several potential risk factors for exposure to HAV including contact with a case

Specimen/lab information (describe):

Travel history (describe):

History of travel outside of state

Other (describe):

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

2-3 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:

Title:

Affiliation:

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:

Name:

Title:

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) 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