

**REQUEST FOR APPROVAL UNDER THE GENERIC CLEARANCE FOR EMERGENCY
CRUISE SHIP OUTBREAK INVESTIGATIONS
(0920-1255)**

Instruction: This form should be completed by the primary contact person from the CDC Vessel Sanitation Program 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 Emergency Cruise Ship Outbreak Investigations (CSOI) generic clearance mechanism. Complete the checklist below. If you select “yes” to all criteria in Column A, the CSOI generic clearance mechanism **can** be used. If you select “yes” to any criterion in Column B, the CSOI generic clearance mechanism **cannot** be used.*

Column A	Column B
The AGE outbreak or event occurs in people on a cruise ship in U.S. jurisdiction. <input type="checkbox"/> Yes <input type="checkbox"/> No	Investigation is not related to cruise travel. <input type="checkbox"/> Yes <input 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 morbidity or mortality). <input type="checkbox"/> Yes <input type="checkbox"/> No	Investigation is related to non-urgent outbreaks or events. <input type="checkbox"/> Yes <input type="checkbox"/> No
The investigation is characterized by undetermined agents, undetermined sources, undetermined modes of transmission, or undetermined risk factors. <input type="checkbox"/> Yes <input type="checkbox"/> No	Investigation is conducted for the primary purpose of program evaluation, surveillance, needs assessment, or research (e.g., research to contribute to generalizable knowledge). <input type="checkbox"/> Yes <input type="checkbox"/> No
One or more CDC staff (including trainees and fellows) will be deployed to the field. <input type="checkbox"/> Yes <input type="checkbox"/> No	CDC staff will not be deployed to the field. <input type="checkbox"/> Yes <input type="checkbox"/> No
Data collection is anticipated to be completed in 30 days or less. <input type="checkbox"/> Yes <input type="checkbox"/> No	Data collection is anticipated to be completed in greater than 30 days. <input type="checkbox"/> Yes <input type="checkbox"/> No

Did you select “Yes” to all criteria in Column A?

If yes, the CSOI generic clearance mechanism 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 CSOI generic clearance mechanism is **NOT** appropriate for your investigation. Stop completing this form now.

TITLE OF INFORMATION COLLECTION: *Instruction: Provide the title of the investigation in the following format: [Undetermined agent, undetermined source, undetermined mode of transmission, undetermined risk factor] for AGE among [Passengers, crew, or both] — [Cruise ship name][voyage number], [Year]*

DESCRIPTION OF THIS SPECIFIC COLLECTION

- 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) passenger and crew cumulative attack rates and a statement about rate of rise; 3) justification as to why this issue requires an urgent response; and 4) 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).*
- Characteristics of Outbreak or Event** (Check all that Apply):

- Undetermined agent
- Undetermined source
- Undetermined mode of transmission
- Undetermined risk factor

3. **Location of Investigation:** *Instruction: Indicate the name of the cruise ship and cruise line on which the investigation will occur.*

Name of Ship:

Cruise line:

4. **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.*

Passengers (describe):

Crew members (describe):

Other (describe):

5. **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.*

6. **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):

Cohort Study (describe):

Case-Control Study (describe):

Other (describe):

Environmental Assessment (describe):

Laboratory Testing (describe):

Other (describe):

8. **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):

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

Other (describe):

Biological Specimen Sample

Environmental Sample

Other (describe):

9. 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):

Medical history (describe):

Risk factors (describe):

Specimen/lab information (describe):

Travel history (describe):

Other (describe):

10. Duration of Data Collection (number of days):

INVESTIGATION LEAD: *Instruction: Indicate the name, title, and affiliation of the person who will be leading the investigation.*

Name:

Title:

Affiliation:

VESSEL SANITATION PROGRAM PRIMARY CONTACT PERSON: *Instruction: Indicate the name, title, and contact information of the VSP Primary Contact Person for this investigation. Indicate the preferred method of contact during the PRA clearance process. Note, contact person or a designee must be available during the PRA clearance process in case questions arise.*

Name of VSP Primary Contact Person:

Title of VSP Primary Contact Person:

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

Office phone:

Home phone:

Cell phone/Blackberry:

E-mail:

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 VSP Primary Contact Person for this Investigation.*

I, [INSERT NAME OF VSP CONTACT], certify the following to be true:

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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.

VSP Primary Contact Name:

Date of Certification:

REQUESTED APPROVAL DATE (MM/DD/YYYY): *Instruction: Indicate the date by which approval is needed.*

DATE SUBMITTED TO INFORMATION COLLECTION REQUEST LIAISON (MM/DD/YYYY):
Instruction: Please indicate the date the request is submitted to the ICRL.

Submit the completed form to the Information Collection Request Liaison (ICRL) in STARS. Send an email to Stephanie Davis, at sgd8@cdc.gov and to the general mailbox at NCEHOMB@cdc.gov, to notify the ICRL to look for the emergency request in STARS. If submitting outside business hours and immediate approval is needed, email and call 770-488-3676 to notify the ICRL of the submission.