



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

Print Date: 10/14/21

Title: Emergency Cruise Ship Outbreak Investigations (CSOIs)
Project Id: 0900f3eb81d9a780
Accession #: NCEH-VSPT-8/9/21-9a780
Project Contact: Keisha A Jenkins
Organization: NCEH/ATSDR/DEHSP/WFEHSB/VSPT
Status: **Project In Progress**
Intended Use: **Project Determination**
Estimated Start Date: 03/31/2021
Estimated Completion Date: 03/31/2022
CDC/ATSDR HRPO/IRB Protocol #:
OMB Control #: No OMB Control Number issued

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research / Other <i>45 CFR 46.102(l)</i> Non-Epi Aids Investigations	9/21/21	Davis_Stephanie I. (sgd8) CIO HSC
PRA:			

PRA Applies		9/21/21	Davis_Stephanie I. (sgd8) CIO OMB / PRA
ICRO: PRA Applies	OMB Approval date: 9/22/21 OMB Expiration date: 12/31/99	9/22/21	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority: Standard

Determination Start Date: 08/09/21

Description:

This is an extension information collection request for the #Emergency Cruise Ship Outbreak Investigations (CSOIs)# (OMB Control Number 0920-1255; expiration date 03/31/2022). The purpose of this ICR is to allow CDC to conduct CSOIs of AGE outbreaks or when unusual AGE illness clusters occur. The VSP deploys to the field and conducts CSOIs to assist cruise industry partners as they respond to AGE outbreaks or events on their vessels. Data collection instruments and methods must be rapidly created and implemented to direct appropriate public health action. Under this generic clearance, CDC will seek emergency PRA clearance for each CSOI within 24-hours of submission to OMB. The data collection period for each CSOI will not exceed 30 days.

IMS/CIO/Epi-Aid/Chemical Exposure Submission: No

IMS Activation Name: Not selected

Primary Priority of the Project: Not selected

Secondary Priority(s) of the Project: Not selected

Task Force Associated with the Response: Not selected

CIO Emergency Response Name: Not selected

Epi-Aid Name: Not selected

Assessment of Chemical Exposure Name: Not selected

Goals/Purpose

The goal of the emergency cruise ship outbreak investigations (CSOIs) is to rapidly determine unknown agents, source, risk factors, and/or mode of transmission for acute gastroenteritis (AGE) illness outbreaks on cruise ships in the U.S. jurisdiction.

Objective: Data will be used to identify AGE outbreak cause and provide public health recommendations for prevention and control.

Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and /or decreasing disparities?: No

Project does not incorporate elements of health equity science: Yes

Measuring Disparities: Not Selected

Studying Social Determinants of Health (SDOH): Not Selected

Assessing Impact: Not Selected

Methods to Improve Health Equity Research and Practice: Not Selected

Other: Not Selected

Activities or Tasks: New Collection of Information, Data, or Biospecimens

Target Populations to be Included/Represented: Other - Cruise ship passengers and crew

Tags/Keywords: Outbreak investigation

CDC's Role: CDC employees or agents will obtain data by intervening or interacting with participants

Method Categories: Outbreak Investigation

Methods: Methods used include retrospective cohort or case control design, health questionnaire, and personal interview.

Collection of Info, Data or Biospecimen: health and exposure questionnaires

Expected Use of Findings/Results: VSP will analyze data using frequencies, proportions, measures of association (e.g., chi-square), odds ratios, and relative risk ratios.

Could Individuals potentially be identified based on Information Collected? No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
Other-	Staff Time Only				0.00

HSC Review

HSC Attributes

Non-Epi Aids Investigations

Yes

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office No

Estimated number of study participants

Population - Children

Population - Minors

Population - Prisoners

Population - Pregnant Women

Population - Emancipated Minors

Suggested level of risk to subjects Do you anticipate this project will be exempt research or non-exempt research

Requested consent process wavers

Informed consent for adults No Selection

Children capable of providing assent No Selection

Parental permission No Selection

Alteration of authorization under HIPPA Privacy Rule No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults No Selection

Children capable of providing assent No Selection

Parental permission No Selection

Consent process shown in an understandable language

Reading level has been estimated No Selection

Comprehension tool is provided No Selection

Short form is provided No Selection

Translation planned or performed No Selection

Certified translation / translator No Selection

Translation and back-translation to/from target language(s) No Selection

Other method No Selection

Clinical Trial

Involves human participants No Selection

Assigned to an intervention No Selection

Evaluate the effect of the intervention No Selection

Evaluation of a health related biomedical or behavioral outcome No Selection

Registerable clinical trial No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus No Selection

Human genetic testing is planned now or in the future No Selection

Involves long-term storage of identifiable biological specimens No Selection

Involves a drug, biologic, or device No Selection

Conducted under an Investigational New Drug exemption or Investigational Device Exemption No Selection

Institutions & Staff

Institutions

Name	FWA #	FWA Exp Date	IRB Title	IRB Exp Date	Funding #
Centers for Disease Control & Prevention	FWA00001413	07/30/26			

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Keisha Jenkins	n/a	n/a	n/a	n/a	Program Official	brn0@cdc.gov	770-488-3096	

Data

DMP

Proposed Data Collection Start Date: 4/1/22

Proposed Data Collection End Date: 3/31/25

Proposed Public Access Level: Non-Public, Restricted

Non-Public Details:

Reason For Not Releasing Data: CIO conducting this project does not fund or own the data and is not responsible for making it available

Restricted Details:

Data Use Type: Data Sharing Agreement

Data Use Type URL:

Data Use Contact:

Public Access Justification: Voyage information and individual level data will not be made available to the public. Data is owned by the cruise company. Only cumulative gastroenteritis case counts for passengers and crew is available for restricted sharing.

How Access Will Be Provided for Data: Deidentified Excel worksheet

Plans for Archival and Long Term Preservation:

Spatiality

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Country	State/Province	County/Region
United States		

Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									



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