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 *45 CFR 46.102(l)* 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 waviers

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 identfiable 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

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...