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

Print Date: 2/27/25

Title:	Emergency Cruise Ship Outbreak Investigations (CSOIs)
Project Id:	0900f3eb81d9a780
Accession #:	NCEH-VSPT-8/9/21-9a780
Project Contact:	Stefanie B White
Organization:	NCEH/ATSDR/DEHSP/WFEHSB/VSPT
Status:	**Project In Progress : PRA Revision**
Intended Use:	**Project Determination**
Estimated Start Date:	03/31/2021
Estimated Completion Date:	03/31/2022
CDC/ATSDR HRPO/IRB Protocol #:	
OMB Control #:	0020-1255

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	11/5/24	Ding_Yan (Shirley) (yad6) CIO HSC
PRA: **PRA Applies**		11/5/24	Ding_Yan (Shirley) (yad6) CIO OMB / PRA
ICRO: **PRA Applies**	OMB Approval date: 3/18/22 OMB Expiration date: 3/31/25	11/6/24	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority: Standard

Priority Justification:

CDC Priority Area for this Project: Not selected

Determination Start Date: 12/14/21

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 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/Lab-Aid/Chemical Exposure Submission: No

IMS Activation Name: Not selected

Submitted through IMS Clearance Matrix: Not selected

Primary Scientific Priority: Not selected

Secondary Scientific Priority (s): Not selected

Task Force Responsible: Not selected

CIO Emergency Response Name: Not selected

Epi-Aid Name:	Not selected
Lab-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. This project addresses Objective 1 of the DEHSP Science Agenda: Identify and develop environmental health data sets, methodologies, and tools to assess exposures, health outcomes, and public health actions (Category 1: High impact, low effort).
Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?:	No
Does your project investigate underlying contributors to health inequities among populations /groups experiencing social, economic, geographic, and/or environmental disadvantages?:	No
Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?:	No
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 ; cruise ; Gastroenteritis
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 and their impact:	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 require review by a CDC IRB or HRPO? No

Estimated number of study participants

Population - Children Protocol Page #:

Population - Minors Protocol Page #:

Population - Prisoners Protocol Page #:

Population - Pregnant Women Protocol Page #:

Population - Emancipated Minors Protocol Page #:

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 HIPAA 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

Will you be working with an outside Organization or Institution? Yes

Institution	FWA #	FWA Exp Date	Funding	Funding Restriction Amount
Centers for Disease Control & Prevention	FWA00001413	05/30/29		

Institution	Funding Restriction Percentage	Funding Restriction Reason	Funding Restriction has been Lifted
Centers for Disease Control & Prevention			

Institution	Institution Role(s)	Institution Project Title	Institution Project Tracking #	Prime Institution
Centers for Disease Control & Prevention				

Institution	Regulatory Coverage	IRB Review Status
Centers for Disease Control & Prevention		

Institution	Registered IRB	IRB Registration Exp. Date	IRB Approval Status
Centers for Disease Control & Prevention			

Institution	IRB Approval Date	IRB Approval Exp. Date	Relying Institution IRB
Centers for Disease Control & Prevention			

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	CITI Good Laboratory Practice Exp. Date	Staff Role	Email	Phone	Organization
Leigh Ellyn Preston	n/a	n/a	n/a	n/a	n/a	Co-Investigator	poe2@cdc.gov		Centers for Disease Control & Prevention

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...									

Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
	Zirger_Jeffrey (wtj5) ICRO Reviewer	11/06/2024	NOA 0920-1255 (2022)	Notice of Action	NOA 0920-1255_2022.pdf
Current	White_Stefanie B. (ixy3) Project Contact	10/29/2024	60-day FRN Publication Request Form	Other, 0.1260 Request to End Review of Human Research Studies	0 - 60-day FRN Publication Request Form VSP CSOI 10-29-2024.docx
Current	White_Stefanie B. (ixy3) Project Contact	10/29/2024	FRN	Other, 0.1260 Request to End Review of Human Research Studies	0 - 60-day_FRN_CDC_Template_VSP CSOI 10-24-2024.docx
Current	White_Stefanie B. (ixy3) Project Contact	10/29/2024	FRN: Sample Consent	Consent Form, 0.1260 Request to End Review of Human Research Studies	Consent Forms Sample.docx
Current	White_Stefanie B. (ixy3) Project Contact	10/29/2024	FRN: Example Questionnaire	Data Collection Form, 0.1260 Request to End Review of Human Research Studies	AGE Example Questionnaire.docx
Current	White_Stefanie B. (ixy3) Project Contact	10/29/2024	FRN: Semi-structures Interview Guide Example	Data Collection Form, 0.1260 Request to End Review of Human Research Studies	Semi-structured Interview Guide Example.docx
Current	White_Stefanie B. (ixy3) Project Contact	10/29/2024	60-day FRN Publication Request Form	Other, 0.1260 Request to End Review of Human Research Studies	0 - 60-day FRN Publication Request Form VSP CSOI 10-29-2024.docx
Current	White_Stefanie B. (ixy3) Project Contact	10/29/2024	FRN	Other, 0.1260 Request to End Review of Human Research Studies	0 - 60-day_FRN_CDC_Template_VSP CSOI 10-24-2024.docx
Current	White_Stefanie B. (ixy3) Project Contact	10/29/2024	FRN: Sample Consent	Consent Form, 0.1260 Request to End Review of Human Research Studies	Consent Forms Sample.docx
Current	White_Stefanie B. (ixy3) Project Contact	10/29/2024	FRN: Example Questionnaire	Data Collection Form, 0.1260 Request to End Review of Human Research Studies	AGE Example Questionnaire.docx
Current	White_Stefanie B. (ixy3) Project Contact	10/29/2024	FRN: Semi-structures Interview Guide Example	Data Collection Form, 0.1260 Request to End Review of Human Research Studies	Semi-structured Interview Guide Example.docx
	Zirger_Jeffrey				

	(wtj5) ICRO Reviewer	12/22/2021	NOA 0920-1255 (2019)	Notice of Action	NOA 0920-1255.pdf
	Foster_Stephanie L. (sob4) Division Approver Projects	12/20/2021	Adding zip package per discussion with Stephanie Davis. Please note an additional comment to Pt1Wksht_CSOIs 2022 20211215. pdf that I added regarding PII following discussion and confirmation with the program.	Other	0920-1255 2022 CSOI Rev 20211215 to ICRO_v2.zip
	Jenkins_Keisha A. (brn0) Project Contact	12/14/2021	30-day ICR Zip file	Paperwork Reduction Act Form	0920-1255 2022 CSOI Revision draft 20211119.zip
	Zirger_Jeffrey (wtj5) ICRO Reviewer	09/22/2021	NOA 0920-1255 (2019)	Notice of Action	NOA 0920-1255.pdf
	Davis_Stephanie I. (sgd8) CIO OMB / PRA	09/21/2021	60-day FRN publication request package	Paperwork Reduction Act Form	CSOI 60D 2021 to ICRO.zip
	Jenkins_Keisha A. (brn0) Project Contact	09/21/2021	60-day Package	Other	CSOI 60D 2021 rev OS_kj.zip
	Davis_Stephanie I. (sgd8) CIO HSC	09/16/2021	60-day package with OS edits	Paperwork Reduction Act Form	CSOI 60D 2021 rev OS.zip
	Jenkins_Keisha A. (brn0) Project Contact	08/09/2021	Folder includes attachments	Other-ICR Package	CSOI ICR package_2021.zip