



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

Print Date: 9/16/25

Title:	U.S. National Authority for Containment of Poliovirus Data Collection Tools
Project Id:	0900f3eb8225c620
Accession #:	-CPR-11/1/23-5cf7f
Project Contact:	Albert D Garcia
Organization:	ORR
Status:	Pending Regulatory Clearance
Intended Use:	Project Determination
Estimated Start Date:	11/01/2023
Estimated Completion Date:	11/01/2027
CDC/ATSDR HRPO/IRB Protocol #:	
OMB Control #:	0920-1424
OMB Discontinuation Date:	

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research - Public Health Surveillance <i>45 CFR 46.102(l)(2)</i> Not Research / Other <i>45 CFR 46.102(l)</i> Environmental Sampling	11/1/23	Garcia_Albert D. (asg9) CIO HSC
PRA: PRA Applies		11/1/23	Garcia_Albert D. (asg9) OMB / PRA
ICRO: PRA Applies	OMB Approval date: 12/19/23 OMB Expiration date: 12/31/26	12/16/24	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority: Standard

Date Needed: 11/11/2023

Priority Justification:

CDC Priority Area for this Project: Not selected

Determination Start Date: 11/01/23

Description: The goal of the project is to collect data in the event of a poliovirus breach of containment - as well as to understand the biosafety practices of facilities working on poliovirus and mitigations strategies in place to reduce risks. These goals are in line with World Health Organization's Global Action Plan (GAP) for Poliovirus containment efforts.

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	This information will assist with meeting the goals of the Section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264) and prevents the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.
Objective:	The goal of the project is to collect data in the event of a poliovirus breach of containment - as well as to understand the biosafety practices of facilities working on poliovirus and mitigations strategies in place to reduce risks. These goals are in line with World Health Organization's Global Action Plan (GAP) for Poliovirus containment efforts.
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 - Poliovirus Essential Facilities
Tags/Keywords:	Poliovirus ; Personal Protective Equipment ; Containment of Biohazards
CDC's Role:	Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided
Method Categories:	Needs Assessment; Survey
Methods:	The Facility Incident Reporting Forms for Poliovirus Release and Potential Exposure and Theft and Loss, the Global Action Plan (GAP) Poliovirus Containment Poliovirus-Essential Facility Assessment Checklist, the Global Action Plan (GAP) Poliovirus Containment Poliovirus-Essential Facility Questionnaire, and the Poliovirus Containment Sampling Points and Sanitation Assessment Form for Wastewater (WW) Systems Supporting a Poliovirus-Essential Facility (PEF) in the United States will be in a fillable form and include a paper and electronic based format. The NAC-NIOSH Personal Protective Equipment Survey for Laboratories will be a web based electronic survey using an anonymous REDCap survey. The Facility Incident Reporting Forms for Poliovirus Release and Potential Exposure and Theft and Loss, the Global Action Plan (GAP) Poliovirus Containment Poliovirus-Essential Facility Assessment Checklist, the Global Action Plan (GAP) Poliovirus Containment Poliovirus-Essential Facility Questionnaire, and the Poliovirus Containment Sampling Points and Sanitation
Collection of Info, Data or Biospecimen:	

Assessment Form for Wastewater (WW) Systems Supporting a Poliovirus-Essential Facility (PEF) in the United States will be in a fillable form and include a paper and electronic based format. The NAC-NIOSH Personal Protective Equipment Survey for Laboratories will be a web based electronic survey using an anonymous REDCap survey.

Data captured on the Facility Incident Reporting Form for Poliovirus Release and Potential Exposure will be used in the U.S. NAC risk assessments and guide federal emergency response efforts. # Data captured on the Facility Incident Reporting Form for Poliovirus Theft and Loss will be used in the U.S. NAC risk assessments and guide federal emergency response efforts. # The information collected in the Personal Protective Equipment Survey for Laboratories will assist the Centers for Disease Control and Prevention (CDC), U.S. NAC and National Institute for Occupational Safety and Health (NIOSH) with developing guidance and recommendations for PPE selection and use in support of poliovirus containment as well as identify laboratory PPE commonly used to evaluate laboratory PPE performance characteristics in testing studies. # Information collected in the Global Action Plan (GAP) Poliovirus Containment Poliovirus-Essential Facility Assessment Checklist will aid U.S. facilities in preparing for an audit to obtain a poliovirus certificate of containment. # Data collected from the Global Action Plan (GAP) Poliovirus Containment Poliovirus-Essential Facility Questionnaire will collect additional information on poliovirus materials held by a U.S. facility, their work activities, and facility features. # The Poliovirus Containment Sampling Points and Sanitation Assessment Form for Wastewater (WW) Systems Supporting a Poliovirus-Essential Facility (PEF) in the United States will collect information to assess poliovirus essential facility's wastewater system, the primary safeguards to reduce and control the release of poliovirus from the facility. In addition, it will verify the safeguards of local wastewater utilities that receive wastewater from the PEF.

Expected Use of Findings/Results and their impact:

Could Individuals potentially be identified based on Information Collected?	Yes
Will PII be captured (including coded data)?	Yes
Does CDC have access to the identifiers (including coded data)?:	Yes
Is this project covered by an Assurance of Confidentiality?	No
Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?	No
Is there a formal written agreement prohibiting the release of identifiers?	No

Funding

Funding yet to be added

HSC Review

HSC Attributes

Environmental Sampling 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 wavier

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 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

Will you be working with an outside Organization or Institution? No

Institutions yet to be added

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
Lia Haynes	08/23 /2026					Program Official	loh5@cdc.gov	404-718-4639	OFFICE OF THE CHIEF MEDICAL OFFICER
Suganthi Suppiah	10/07 /2027	10/15/2024				Principal Investigator	kpe9@cdc.gov	404-718-3461	NATIONAL AUTHORITY FOR CONTAINMENT OF POLIOVIRUS

Data

DMP

Proposed Data Collection Start Date: 11/1/23

Proposed Data Collection End Date: 11/1/27

Proposed Public Access Level: Non-Public

Non-Public Details:

Reason For Not Releasing Data: Other - Data is used to mitigate release of poliovirus and has no utility to the public.

Public Access Justification: Data is used to mitigate release of poliovirus and has no utility to the public.

How Access Will Be Provided for Data: Access to the data will be protected via access to the CDC server. The U.S. NAC may share information about the incident to poliovirus containment oversight bodies and CDC Incident Response leadership to ensure appropriate measures are implemented.

Plans for Archival and Long Term Preservation: CDC/CPR/OD/NAC is the steward for the data. Data collected will be stored on a shared drive within CDC's secured environment with restricted access.

Spatiality

Country	State/Province	County/Region
United States		

Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	Landing Page URL	Direct 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	12/16/2024	NOA 0920-1424 (2023)	Notice of Action	NOA 0920-1424_2023.pdf
Current	Garcia_Albert D. (asg9) Project Contact	11/01/2023	PPE Lab Survey	Data Collection Form	Att7 - _Personal Protective Equipment Survey for Laboratories_Final.pdf
Current	Garcia_Albert D. (asg9) Project Contact	11/01/2023	GAP Questionnaire	Data Collection Form	Att6 - Global Action Plan (GAP) Poliovirus Containment Poliovirus-Essential Facility Questionnaire_Final.pdf
Current	Garcia_Albert D. (asg9) Project Contact	11/01/2023	GAP PEF Assessment	Data Collection Form	Att4 5-Global Action Plan (GAP) Poliovirus Containment Poliovirus-Essential Facility Assessment Checklist_Final.pdf
Current	Garcia_Albert D. (asg9) Project Contact	11/01/2023	Release or Potential Exposure	Data Collection Form	Att3 - Facility Incident Reporting Form for Poliovirus Release or Potential Exposure_final.pdf
Current	Garcia_Albert D. (asg9) Project Contact	11/01/2023	Wastewater Assessment	Data Collection Form	Att8_Poliovirus Containment Sampling Points and Sanitation Assessment Form for Wastewater_Final.pdf
Current	Garcia_Albert D. (asg9) Project Contact	11/01/2023	Theft or Loss	Data Collection Form	Att4 - Facility Incident Reporting Form for Poliovirus Theft or Loss_Final.pdf



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