



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

Print Date: 2/24/25

Title: Poliovirus Facility Response Readiness Survey

Project Id: 0900f3eb824c489a

Accession #: ORR-NAC-12/18/24-c489a

Project Contact: Cecelia A Sanders

Organization: ORR/DRSC/NAC

Status: Pending Clearance

Intended Use: Project Determination

Estimated Start Date: 12/18/2024

Estimated Completion Date: 12/31/2026

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #: 0920-1154

Determinations

| Determination | Justification | Completed | Entered By & Role |
|---|---|-----------|---------------------------------|
| HSC: Does NOT Require HRPO Review | Not Research / Other <i>45 CFR 46.102(l)</i> Other - Program improvement and tool development | 2/3/25 | Garcia_Albert D. (asg9) CIO HSC |

Description & Funding

Description

Priority: Standard

Date Needed: 02/01/2025

Priority Justification:

CDC Priority Area for this Project: Readiness and Response

Determination Start Date: 01/13/25

Description:

As the world approaches eradication of poliovirus (PV) and given the 2022 case of vaccine-derived polio in the United States, the first since 2013, poliovirus response readiness has moved to the forefront of planning for many within the emergency response community. Facilities in the U.S. that work with or store poliovirus must register with the U.S. National Authority for Containment of poliovirus (NAC), implement appropriate risk mitigation strategies, and be prepared to respond to poliovirus-related incidents including worker exposure, release, theft, loss, or other breach of containment. The U.S. NAC works with registered poliovirus essential facilities (PEF) to ensure that stringent biocontainment measures required in the WHO Poliovirus Global Action Plan (GAP) are in place. Poliovirus has unique handling and containment needs, and response plans developed by PEFs must reflect deliberate and informed planning to protect workers and ensure timely and effective response to poliovirus-related emergencies. However, since 2018, only 8.2% of NAC-audited facilities fully met the emergency planning and response requirements of GAP. Additionally, NAC data suggest that gaps in preparedness and response readiness of U.S. facilities could delay or hinder efforts to respond to a poliovirus incident. To address this problem, the U.S. NAC has developed an online tool in consultation with emergency response, communication, and survey design experts, for facilities to assess their current level of poliovirus preparedness and response readiness. This self-led tool navigates users through a series of questions on topics such as available resources and practices for planning, training, and exercises; communication and evaluation plans; incident investigation procedures; documentation of strengths, areas for improvement, and lessons learned; and ability to manage and resolve identified improvement plan tasks after an exercise or incident. Participants using the tool are presented with recommendations for improving their current response capabilities and offered information on training, guidance, and other resources tailored to their situation based on the responses they provided to questions in seven broad categories. Facilities can also indicate interest in participating in poliovirus outbreak simulation exercises with inter-agency state and federal partners. This new tool offers facilities an opportunity to improve their internal response readiness therefore putting local, state, and national public health authorities better positioned to address patient/sample testing, transmission, surveillance, environmental concerns, community messaging, and other issues when faced with a poliovirus incident.

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 | <p>The goal of the survey is to ascertain the level of readiness of poliovirus essential facilities (PEF) for responding to a poliovirus breach of containment or other polio-related event and provide PEFs with information that will help them to improve their preparedness and response plans. Additionally, NAC program will be improved by using the anonymous data to identify common and significant areas for improvement and focus limited resources on activities that will have the greatest positive impact on the PEF community.</p> |
| Objective: | <p>The NAC will introduce poliovirus essential facilities (PEF) to the survey in a webinar on 1/29/2025 and request volunteers to participate in a pilot launch of the survey. The pilot survey will be distributed to a small group of PEFs in February 2025 to gain feedback on the design, questions, and post-survey resources report. Once feedback is reviewed and addressed, and OMB/PRA clearance is complete, the NAC will begin broader distribution in April 2025. While initial distribution will be limited to U.S. facilities, it is the intent of the program to coordinate with WHO to share the survey questions/platform with country/regional NACs for further distribute to their respective PEFs (details of the global distribution are pending). The U.S. NAC will lead the analysis of the global data and provide aggregate results to the WHO Containment Team and NACs, identifying challenges and other common areas for improvement as reported by the PEFs.</p> |
| 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: | Businesses |
| Tags/Keywords: | Poliovirus ; Surveys and Questionnaires |
| CDC's Role: | CDC employees or agents will obtain or use anonymous or unlinked data or biological specimens |
| Method Categories: | Survey |
| Methods: | <p>NAC will utilize a web-based survey to collect data and provide a post-survey report with information on available resources, tailored to the PEF based on the responses provided. Responses are provided anonymously. Branching logic is utilized to reduce the time needed to complete the survey questions.</p> |
| Collection of Info, Data or Biospecimen: | <p>NAC will utilize the REDCap software in the anonymous environment. The survey is comprised of 77 questions subdivided by modules and sections. Responses are provided anonymously. Branching logic will be utilized to reduce the time needed by respondents to complete the survey questions.</p> |

Expected Use of Findings/Results and their impact:

Survey results will be used to improve the containment program by focusing the NAC's available resources on the development of policies, guidance, and training for PEFs based on the most commonly reported and highest risk areas as reported by respondents. These products along with the informational resources provided in the post-survey report will be a valuable asset to PEFs and the result of the effort is a PEF community better prepared to respond to a poliovirus breach of containment or other poliovirus-related event.

Could Individuals potentially be identified based on Information Collected? No

Funding

Funding yet to be added

HSC Review

HSC Attributes

Other - Program improvement and tool development 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 | N/A | Protocol Page #: |
| Population - Minors | N/A | Protocol Page #: |
| Population - Prisoners | N/A | Protocol Page #: |
| Population - Pregnant Women | N/A | Protocol Page #: |

Population - Emancipated Minors

N/A

Protocol Page #:

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 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 |
|----------------------|----------------|---------------------------|------------------------------------|---------------------------------------|---|------------------|--------------|--------------|--|
| Bryan Shelby | 06/26 /2026 | | | | | Co-Investigator | gvr1@cdc.gov | 404-639-1395 | NATIONAL AUTHORITY FOR CONTAINMENT OF POLIOVIRUS |
| Cecelia Sanders | 11/09 /2026 | | | | | Co-Investigator | zfg0@cdc.gov | 404-639-5131 | NATIONAL AUTHORITY FOR CONTAINMENT OF POLIOVIRUS |
| Christy Ottendorfer | 09/12 /2026 | | | | | Co-Investigator | uyk0@cdc.gov | 404-639-7179 | NATIONAL AUTHORITY FOR CONTAINMENT OF POLIOVIRUS |
| Kortney Gustin | 07/18 /2026 | | | | | Co-Investigator | ihe9@cdc.gov | 404-639-3545 | NATIONAL AUTHORITY FOR CONTAINMENT OF POLIOVIRUS |
| Lia Haynes | 08/23 /2026 | | | | | Program Official | loh5@cdc.gov | 404-718-4639 | DIVISION OF REGULATORY SCIENCE AND COMPLIANCE |
| Patrick Vander Kelen | 08/04 /2026 | | | | | Co-Investigator | lup8@cdc.gov | 404-718-5408 | NATIONAL AUTHORITY FOR CONTAINMENT OF POLIOVIRUS |
| Suganthi Suppiah | 10/07 /2027 | 10/15/2024 | | | | Co-Investigator | kpe9@cdc.gov | 404-718-3461 | NATIONAL AUTHORITY FOR CONTAINMENT OF POLIOVIRUS |

Data

DMP

Proposed Data Collection Start Date: 5/5/25

Proposed Data Collection End Date: 12/31/27

Proposed Public Access Level: Non-Public

Non-Public Details:

Reason For Not Releasing Data:

Other - No utility for the general population

Public Access Justification:

Data has no utility for the broader population. Survey results may be shared with the Poliovirus Containment Working Group (PCWG) or CDC/ORR leadership in aggregate form (i.e., summarizing data at group level, not individual facility level). No PII will be collected.

How Access Will Be Provided for Data:

Data will be collected and stored in REDCap (short-term). Long-term, all data will be transferred to and stored in NAC#s Azure SQL database behind the CDC firewall. The NAC Director and/or technical owner will determine who is permitted to have access to the REDCap project and data. A decision to grant access is based on an individual's need to know and is conveyed to the REDCap project manager and SQL database business owner to grant access rights within the systems. Access to the system and its data is permissions-based and controlled by the technical owner using the Principal of Least-Privilege as the model for access control. Access to certain application features is only available to an individual if their CDC PIV card profile at login is a match to one documented within the system. All system users are required to take security awareness and privacy training on an annual basis. Furthermore, users will receive system-specific training based on their NAC role(s) and responsibilities to further their skills and perform their specific jobs in a secure manner.

Plans for Archival and Long Term Preservation:

The data will be retained throughout the life of the project and then deleted once it is determined that it has no additional value for the NAC.

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 |
|---------|--|------------|--|----------------------|---|
| Current | Sanders_Cecelia (zfg0) Project Contact | 01/13/2025 | This file includes the survey questions with response options, and examples of two summary reports (onscreen and via download) that a respondent will be offered at the end of the survey. | Data Collection Form | Poliovirus Response Readiness Survey_13Jan2025.docx |



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