



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

Print Date: 11/1/23

Title: U.S. National Authority for Containment of Poliovirus Data Collection Tools
Project Id: 0900f3eb8225cf7f
Accession #: -CPR-11/1/23-5cf7f
Project Contact: Albert D Garcia
Organization: CPR
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 #:

Determinations

| Determination | Justification | Completed | Entered By & Role |
|---|--|-----------|-----------------------------------|
| HSC: Does NOT Require HRPO Review | Not Research - Public Health Surveillance <i>45 CFR 46.102(1)(2)</i> Not Research / Other <i>45 CFR 46.102(1)</i> Environmental Sampling | 11/1/23 | Garcia_Albert D. (asg9) CIO HSC |
| PRA: PRA Applies | | 11/1/23 | Garcia_Albert D. (asg9) OMB / PRA |

Description & Funding

Description

| | |
|--|---|
| Priority: | Standard |
| Date Needed: | 11/01/2023 |
| 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 |
| 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 |
| 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 |

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|--|--|
| 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. |
| Collection of Info, Data or Biospecimen: | 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. |
| Expected Use of Findings/Results and their impact: | <ul style="list-style-type: none"> • 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. |
| Could Individuals potentially be identified based on Information Collected? | Yes |
| Will PII be captured (including coded data)? | Yes |

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|---|-----|
| 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

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|-------------------------------|-----|
| Environmental Sampling | Yes |
|-------------------------------|-----|

Regulation and Policy

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|---|----|
| Do you anticipate this project will need IRB review by the CDC IRB, NIOSH IRB, or through reliance on an external IRB? | 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 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

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 | 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 | 09/28/2025 | 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 | 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 | 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 |

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|---------|--|------------|-------------------------------|----------------------|---|
| Current | Garcia_Albert D. (asg9) Project Contact | 11/01/2023 | GAP PEF Assessment | Data Collection Form | Att5-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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