National Inventory for Poliovirus Containment: Minimizing Risk of Poliovirus Release from Laboratories in the United States

The US Poliovirus National Authority for Containment of Poliovirus (NAC), located in the Centers for Disease Control and Prevention, Center for Preparedness and Response, appreciates your participation in this survey. This survey is designed to collect relevant laboratory inventory data to ensure compliance with requirements established in the WHO Global Action Plan (GAPIII), as adapted for the WHO Region of the Americas. Per GAPIII, each country is required to complete a national inventory of poliovirus-containing materials. Unlike previous surveys, the 2018 survey focuses on institutions that may have poliovirus potentially infectious materials (PIM). PIM includes human respiratory secretion and fecal specimens collected for non-polio related work in a time and place where wild poliovirus (WPV) or vaccine-derived poliovirus (cVDPV) was circulating or where oral polio vaccine (OPV) was in use. Historical domestic and international specimens are more likely to fall into these categories. Additionally, PIM cultured in some common cell lines (*see Appendix C: Common Cell Lines and Animals Susceptible to Poliovirus*) in order to isolate other viruses of interest may have unintentionally amplified poliovirus, so respiratory or enteric viral isolates obtained from PIM specimens using any of these cell lines are also considered PIM.

Historical and international specimen collections are more likely to contain poliovirus than other collections

See "Guidance for non-poliovirus facilities to minimize risk of sample collections potentially infectious for poliovirus" (WHO, 2018)

The survey should be completed by laboratories, storage sites, or other facility types that test, extract, handle, or store biological samples from humans, experimentally infected animals, sewage, or environmental waters. The survey questions are intended to identify facilities that possess any materials that may contain poliovirus. The questions seek to distinguish between PIM containing wild poliovirus (WPV), circulating vaccine derived poliovirus (cVDPV), and oral poliovirus vaccine (OPV). With the release of the WHO PIM guidance in April 2018, extracted nucleic acid and specimens that **may contain only OPV** are no longer subject to containment under WHO GAP III. However, they are still considered to be part of the US inventory and should be reported.

For the purpose of this survey, PIM should be identified on the basis of where and when the specimens were collected, not on the basis of any test results (*see WHO's Annex 2: Country and Territory-Specific Poliovirus Data*). If your facility intends to destroy all of the potentially infectious poliovirus material or infectious material it possesses, you will then be asked to complete an attestation of destruction of the material. This attestation form will be sent to you once the completed survey is received.

Survey Instructions

This survey is divided into six modules:

A. Facility Information
B. Material Types
C. Inventory Information
D. Disposition of Materials
E. Key Facility Personnel
F. Attestation

Throughout the survey, questions requiring a single answer are indicated by a circle (○) and check boxes (□) are used if multiple answers are permitted. Instructions are provided with some questions. Definitions of key words used here and in the online survey can be found in **Appendix A**. Please pay close attention to the instructions at the end of modules A and B, as these will determine whether modules C and D need to be completed. Modules E and F will be completed by all survey recipients. The time needed to complete the online survey will vary depending on the complexity of your facility and the availability of needed information.

This document has been provided to help you prepare your survey responses. It is not intended to be used as a substitute for completing the online version of the survey. Please do not submit this paper version, as the survey must be completed online. If you begin the survey and then terminate it early, you will be provided with a return code via email. Click the survey link and enter the code when prompted by the system.

Please contact poliocontainment@cdc.gov immediately if you have any questions about the survey or the questions it contains and someone will provide assistance.

Module A – Facility Information

Module A: Section 1: Information about the Parent Institution

The questions in Module A: Sections 1 and 2 inquire about the parent institution, facility, or company to which your specific laboratory belongs. Starting with Section 3, questions are laboratory specific.

1.1 Name of Parent Institution _____

1.2 Name of Department, School, Center, etc. (*if applicable*) _____

1.3 Physical address of parent institution (no mailing or P.O. Box addresses) _____

1.4 City _____ 1.5 State/Territory _____ 1.6 Zip Code _____

1.7 Please tell us how you learned about the nation poliovirus survey (*select all that apply*)

- ☐ American Academy of Pediatrics
- ☐ American Association for Advancement of Science
- ☐ American Association for Laboratory Animal Science
- ☐ American Biological Safety Association
- ☐ American Institute of Biological Sciences
- ☐ American Public Health Association
- ☐ American Society for Clinical Laboratory Science
- ☐ American Society for Clinical Pathologists
- ☐ American Society for Laboratory Animal Practitioners
- ☐ American Society for Microbiology
- ☐ American Society for Tropical Medicine and Hygiene
- ☐ American Society for Virology
- ☐ American Water Works Association
- ☐ Association of Clinical Research Professionals
- ☐ Association of Independent Research Institutes
- ☐ Association of Public Health Laboratories
- ☐ Clinical Laboratory Management Association
- ☐ College of American Pathologists
- ☐ Federation of American Societies for Experimental Biology
- ☐ Foundation for Biomedical Research
- ☐ Infectious Diseases Society of America
- ☐ National Association of Biomedical Research
- ☐ National Science Foundation William J. Cooper
- ☐ Pharmaceutical Research and Manufacturers of America
- ☐ Water Research Foundation
- ☐ Contacted by CDC
- ☐ Other _____

Module A: Section 2: Classification of the Institution

2.1. Which of the following best describes the primary funding source for your institution? (select one)

- ○ Public (functions with public resources)
- ○ Private (functions with resources from partners)
- ○ Mixed (functions with both public and private resources)
- ○ Foundation (funded by a foundation or other not-for-profit entity)

2.2. What is the area of influence for this institution's activities? (select all that apply)

- ☐ Education
- ☐ Health care and other areas of health aimed at the civilian population
- ☐ Defense sector (military): clinical and/or research area
- ☐ Environmental laboratory
- ☐ Other _____

2.3 - 2.4 What are the primary and secondary objectives of the institution? Primary (check only one response) Secondary (check all that apply)

Work Objectives	**2.3 Primary** (*select one*)	**2.4 Secondary** (*select all that apply*)
Biomedical research	○	☐
Government public health laboratory	○	☐
Clinical diagnostic laboratory	○	☐
Industrial/Production laboratory (vaccines/biologicals, medicines, etc.)	○	☐
Control or research of wastewater, drinking water, or other natural or artificial water sources	○	☐
Control or research of sewage and/or wastewater management	○	☐
Environmental laboratory	○	☐
Storage of biological samples or biobank	○	☐
Other*_____	○	☐

**If 'other' is selected, please provide a brief description of the work objectives.*

Module A: Section 3: Laboratory or Storage Site Information

Please note that question on this page and throughout the remainder of the survey inquire about the specific laboratory or storage site for which you are reporting.

3.1 Name of the laboratory or storage site _____

If your laboratory address is different than the parent facility, please provide the address below.

3.2 Physical street address _____

3.3 City _____ 3.4 State/Territory _____ 3.5 Zip Code _____

Module A: Section 4: Survey Point of Contact

As the person completing this survey, you will be the point of contact for your facility should the U.S. NAC have any follow up questions. Please provide your contact information below.

4.1 Name of the individual completing the survey (First and Last) _____

4.2 Title of the individual completing the survey _____

4.3 Work Email of the individual completing the survey _____

4.4 Work phone number of the individual completing the survey _____

Module A: Section 5: Specialization of the Laboratory

5.1 Which of the following best describe the area(s) of interest for this laboratory? (Check all that apply)

- ☐ Molecular Biology
- ☐ Virology-poliovirus/enterovirus
- ☐ Virology-gastroenteritis (e.g., rotavirus, norovirus, astrovirus)
- ☐ Virology-respiratory (e.g., influenza, rhinovirus, RSV)
- ☐ Virology-other
- ☐ Bacteriology
- ☐ Mycology
- ☐ Parasitology
- ☐ Pathology
- ☐ Environmental
- ☐ Biology
- ☐ Immunology
- ☐ Public health laboratory
- ☐ Diagnostic/Clinical laboratory
- ☐ Vaccine development
- ☐ Industrial-vaccine production
- ☐ Industrial-vaccine Q/C testing
- ☐ Industrial-general microbiological filter and disinfectant manufacturers
- ☐ Nutrition
- ☐ Bioinformatics/Biotechnology
- ☐ Other _____

5.2 Does the laboratory have the capacity for storing biological samples at temperatures of -20ºC or below? (Yes / No)

5.3 Does the laboratory perform cell or tissue culture? (Yes / No)

If you answered NO to question 5.2, you have COMPLETED the survey for your laboratory. *Please skip to Module E: Key Facility Personnel.* *Otherwise, proceed to MODULE B.*

MODULE B – TYPES OF STORED MATERIALS

The questions in Module B ask about the general type(s) of sample(s) that are worked with or stored in your specific laboratory or storage site.

Definitions for terms used in Module B can be found in the appendices listed on the survey webpage.

Module B: Section 1: General Inventory

Below is a list of specimen/sample types common to many laboratories. The questions in this section help us to determine if you have materials that may be relevant to this this survey.

1. Does your laboratory work with or store any of the types of specimens or samples listed below?

MATERIAL TYPE	YES	NO
CLINICAL SAMPLES OR SPECIMENS		
Samples or Specimens of Human Origin:		
a. Respiratory secretion specimens, collected for any purpose	○	○
b. Fecal specimens, collected for any purpose	○	○
c. Unfixed tissue samples (including autopsy), for any purpose	○	○
Samples or Specimens of Animal Origin:		
d. Experimental animals infected with poliovirus	○	○
e. Unfixed tissues/samples from experimental animals	○	○
Samples or Specimens of Environmental Origin:		
f. Concentrated sewage	○	○
g. Bodies of water (other sources, untreated, natural and artificial)	○	○
h. Untreated surface water	○	○
ISOLATES		
i. Virus isolate(s) of human, animal, or environmental origin	○	○

2. Were all of the specimens or samples selected above collected in the United States? (Yes / No / I don't know)

3. Were all of the specimens or samples which were collected within the United States, collected in the year 2000 or LATER?
   (Yes / No / I don't know)

   NOTE: Samples and specimens collected within the United States after the year 2000 are not subject to containment under GAPIII. Information about international samples and specimens will be addressed in Module C of the survey.

4. Does your laboratory work with or store any of the material types listed below?

MATERIAL TYPE	YES	NO
VIRUSES		
j. Known poliovirus	○	○
k. Novel poliovirus strains* (e.g., novel live attenuated oral poliovirus)	○	○
NUCLEIC ACID		
l. Extracted nucleic acid of a human, animal, or environmental origin	○	○
m. Nucleic acid extracted from poliovirus*		
MATERIALS DERIVED FROM RECOMBINANT NUCLEIC ACIDS OR SYNTHETIC BIOLOGY*		
n. Recombinant or synthetic materials containing poliovirus capsid sequences*	○	○
o. Replication competent derivatives produced in the laboratory with capsid sequences from wild polioviruses, unless demonstrably proven to be safer than Sabin strains.	○	○
p. Replication competent derivatives produced in the laboratory with capsid sequences from OPV/Sabin strains.	○	○

Information and definitions can be found in the appendices listed on the survey webpage.

World Health Organization. (2014). Global action plan III: WHO global action plan to minimize poliovirus facility-associated risk. Geneva, Switzerland: World Health Organization; available at http://polioeradication.org/wp-content/uploads/2016/12/GAPII_2014.pdf

If you responded ***YES*** to questions 2 and 3, and ***NO*** to all material types in question 4, you have COMPLETED the survey for your laboratory. Please skip to Module E: Key Facility Personnel.

If you responded ***NO*** to questions 2 or 3, or if you responded ***YES*** to any question from the table above, proceed to Module C: Inventory of Materials.

MODULE C. INVENTORY OF MATERIALS

The questions in this module ask about the type(s) of sample(s) that are stored in your laboratory or storage site and whether they are known to contain poliovirus (Section 1) or are potentially infectious materials (Section 2).

Definitions for terms used in Module C and a summary of last polio cases by country can be found in the appendices listed on the survey webpage.

Module C: Section 1: Inventory of Poliovirus Infectious Materials

If you indicated having materials belonging to one of more of the following categories, please complete this section.

- Collected outside of the United States
- Collected within the United States prior to the year 2000
- Collected at an unknown time and/or location
- CONFIRMED to be infected with poliovirus or that produce infectious virus

1. Do you have any of the following material types? (Select Yes or No for each material type)

Infectious Materials

-	Material Type	YES	NO
1.1	Clinical materials confirmed to contain poliovirus	○	○
1.1.A	Respiratory secretion specimens known to contain WPV or cVDPV	○	○
1.1.B	Respiratory secretion specimens known to contain Sabin/OPV	○	○
1.1.C	Fecal specimens known to contain WPV or cVDPV	○	○
1.1.D	Fecal specimens known to contain Sabin/OPV	○	○
1.1.E	Other clinical specimens (not fecal or respiratory) known to contain WPV	○	○
1.1.F	Other clinical specimens (not fecal or respiratory) known to contain Sabin/OPV	○	○
1.2	Environmental samples of water or sewage that have tested positive for the presence of poliovirus	○	○
1.3	Isolates from cell cultures and reference strains of poliovirus	○	○
1.4	Seed stocks and infectious materials used in the production of IPV vaccines	○	○
1.5	Seed stocks and infectious materials used in the production of OPV/Sabin vaccines	○	○
1.6	Attenuated poliovirus strains not licensed for use as live vaccines	○	○
1.7	Infected animals or samples of these animals, including transgenic mice containing human poliovirus receptors	○	○
1.8	Genetically modified materials (including materials produced by synthetic biology) that have complete poliovirus capsid sequences	○	○
1.9	Full length enterovirus cDNA or RNA that include sequences of capsid derived from poliovirus	○	○
1.10	Cells persistently infected with virus whose capsid sequences are derived from poliovirus	○	○

If you responded YES to any question from the table above, please indicate in the following table approximately how many vials and/or containers of samples confirmed to be infected with poliovirus or that produce infectious poliovirus are currently stored in your laboratory, storage site, or other facility type. If you responded NO to all questions from the table above, please proceed to the next module.

Module C: Section 2: Inventory of Infectious Materials (Type and Amounts)

Type and Amount of Known Infectious Materials

Thinking about the materials from the table in Module C: Section 1, please provide an approximate number of vials/containers containing infectious material for each sample type below using the amount ranges provided below (e.g., None, 1-99, 100-999).

Please note that if WPV and OPV were both circulating at the time and geographic location where the samples or specimens were collected, enter those materials as WPV.

Estimated number of vials/containers containing infectious poliovirus material *(select one per row)*

	None	1-99	100-999	1,000-4,999	5,000-9,999	10,000-50,000	>50,000
WPV or cVDPV Type 1	○	○	○	○	○	○	○
WPV or cVDPV Type 2	○	○	○	○	○	○	○
WPV or cVDPV Type 3	○	○	○	○	○	○	○
WPV or cVDPV Untyped/Unknown	○	○	○	○	○	○	○
Sabin/OPV Type 1	○	○	○	○	○	○	○
Sabin/OPV Type 2	○	○	○	○	○	○	○
Sabin/OPV Type 3	○	○	○	○	○	○	○
Sabin/OPV Untyped/Unknown	○	○	○	○	○	○	○

Module C: Section 3: Inventory of Potentially Infectious Materials

In the previous questions, you may have indicated having materials collected in a time and place where poliovirus was circulating. Therefore, it is possible that your materials may contain poliovirus even if they were not collected for purposes specifically related to polio.

For questions 1-10, refer to WHO's Annex 2: Country and Territory-Specific Poliovirus Data for dates and geographic locations of last known poliovirus cases by country. Refer to Appendix B for information about last use of trivalent oral polio vaccine (tOPV) by country.

1. Do you have any of the following materials types? (*Select YES or NO for each material type*)

Potentially Infectious Materials

-	Material Type	YES	NO	UNSURE
1.1	**Respiratory** secretion samples collected for any purpose at a time and in a geographic area when **wild poliovirus (WPV)** or **vaccine-derived poliovirus (cVDPV)** was circulating*	○	○	○
1.2	**Respiratory** secretion samples collected for any purpose at a time and in a geographic area where **Sabin/OPV** was being used in routine or supplemental immunization programs**	○	○	○
1.3	**Fecal** specimens collected for any purpose at a time and in a geographic area when **wild poliovirus (WPV)** or **vaccine-derived poliovirus (cVDPV)** was circulating*	○	○	○
1.4	**Fecal** specimens collected for any purpose at a time and in a geographic area where **Sabin/OPV** was being used in routine or supplemental immunization programs**	○	○	○
1.5	Environmental samples of water or sewage that have not been tested for the presence of poliovirus	○	○	-
1.6	Uncharacterized viral isolates from poliovirus susceptible/sensitive cells*** ‡	○	○	○
1.7	Isolates from poliovirus-sensitive cells with cytopathic effect resembling uncharacterized enterovirus from countries which are known or suspected to have had circulation of wild poliovirus or vaccine-derived poliovirus (cVDPV) at the time of collection (see Appendix B for areas and dates)	○	○	○
1.8	Stocks of **respiratory virus*** isolated from specimens collected in a time and geographic location where WPV, Sabin/OPV, or cVDPV was circulating (see Appendix B) and handled under conditions conducive to maintaining the viability or enabling the replication of incidental poliovirus ‡	○	○	○
1.9	Stocks of **enteric virus*** isolated from specimens collected in a time and geographic location where WPV, Sabin/OPV, or cVDPV was circulating (see Appendix B) and handled under conditions conducive to maintaining the viability or enabling the replication of incidental poliovirus ‡	○	○	○
1.10	Nucleic acid extracted from fecal or respiratory secretion specimens, or environmental samples collected for any purpose at a time and in a geographic area with circulating wild poliovirus including cVDPV or OPV/Sabin	○	○	○

Please note that virus (characterized or uncharacterized) derived from respiratory or enteric specimens that were collected in a time and geographic location where WPV/cVDPV was circulating or where OPV was in in use is considered potentially infectious material.

2. Were any of the materials above inoculated into cells or animals susceptible to poliovirus?*** (Yes/No)

*Refer to *WHO's Annex 2: Country and Territory-Specific Poliovirus Data*
**See Appendix B for information about the last use of trivalent OPV by country
***See Appendix C for information about poliovirus susceptible/sensitive cell lines and animals

If you responded YES to any question from the table above, please indicate in the following table approximately how many vials and/or containers of potentially infectious poliovirus materials are currently stored in your laboratory, storage site, or other facility type. Note that the table cells below are not mutually exclusive.

Module C: Section 4: Potentially Infectious Materials

Type and Amount of Potentially Infectious Materials

Thinking about the materials from the table in Module C: Section 1, please provide an approximate number of vials/containers containing potentially infectious material for each sample type below.

Please note that if WPV and OPV were both circulating at the time and geographic location where the samples or specimens were collected, enter those materials as WPV.

Estimated number of vials/containers containing potentially infectious material *(select one per row)*

	None	1-99	100-999	1,000-4,999	5,000-9,999	10,000-50,000	>50,000
WPV or cVDPV Type 1	○	○	○	○	○	○	○
WPV or cVDPV Type 2	○	○	○	○	○	○	○
WPV or cVDPV Type 3	○	○	○	○	○	○	○
WPV or cVDPV Untyped/Unknown	○	○	○	○	○	○	○
Sabin/OPV Type 1	○	○	○	○	○	○	○
Sabin/OPV Type 2	○	○	○	○	○	○	○
Sabin/OPV Type 3	○	○	○	○	○	○	○
Sabin/OPV Untyped/Unknown	○	○	○	○	○	○	○

MODULE D: DISPOSITION OF MATERIALS

The questions in Module D ask about what your facility intends to do with the infectious or potentially infectious materials that are currently worked with or stored at your laboratory.

Module D: Section 1: Proposed Disposition of Infectious and Potentially Infectious Poliovirus Materials

In this section, tell us what you intend to do with the PV or PIM materials that are currently held at your facility. Check all that apply, but please note that laboratories are strongly encouraged to destroy all unneeded materials.

1. What do you intend to do with the infectious and potentially infectious materials that are currently held at your laboratory? (*Check all that apply*)

☐ Destroy Materials ☐ Inactivate Materials ☐ Transfer Materials ☐ Retain Materials

If you selected the 'DESTROY' option above, complete Section 2; if you selected 'INACTIVATE, complete Section 3; if you intend to TRANSFER materials, complete Section 4; and if you intend to RETAIN materials, complete Section 5.

Module D: Section 2: Destroying Material

Tell us about the materials that you plan to destroy. Please note that if you opt to destroy material, you will be contacted by a representative of the U.S NAC and asked to complete an attestation of destruction questionnaire. See Appendix D for information about preferred destruction methods.

If materials contain a combination of virus types, please indicate each type separately. *(check all that apply)*

Material to be Destroyed

	None	Type 1	Type 2	Type 3	Unknown/ Untyped
Infectious Materials					
2.1. WPV or cVDPV	☐	☐	☐	☐	☐
2.2. Sabin/OPV	☐	☐	☐	☐	☐
Potentially Infectious Materials					
2.3 WPV or cVDPV	☐	☐	☐	☐	☐
2.4 Sabin/OPV	☐	☐	☐	☐	☐

2.5 Please provide an explanation of the type of material to be destroyed and the destruction method(s) that will be used.

(Refer to the Appendix D for a description of preferred destruction methods)

Module D: Section 3: Inactivating Material

Tell us about the materials that you plan to inactivate. Please note that you will be contacted by a representative of the NAC and asked to complete a form to document the inactivation of this material.

(check all that apply)

Material to be Inactivated

	None	Type 1	Type 2	Type 3	Unknown/ Untyped
Infectious Materials					
3.1 WPV or cVDPV	☐	☐	☐	☐	☐
3.2 Sabin/OPV	☐	☐	☐	☐	☐
Potentially Infectious Materials					
3.3 WPV or cVDPV	☐	☐	☐	☐	☐
3.4 Sabin/OPV	☐	☐	☐	☐	☐

3.5 You indicated that you plan to inactivate infectious materials (e.g., extraction, gamma irradiation). Please provide a brief statement to explain.

Module D: Section 4: Transferring Poliovirus Material

Tell us about the materials that you plan to transfer but please note that poliovirus materials can only be transferred to a registered poliovirus essential facility (PEF). It is the responsibility of your facility to coordinate with the receiving PEF for the transfer of materials. Please contact the NAC at 404-718-5160 or poliocontainment@cdc.gov to discuss the transfer of any infectious poliovirus or potentially infectious materials.

Materials to be Transferred

4.1. If you intend to transfer samples to another facility, please provide a brief statement including the type and amount of material(s) to be transferred, the anticipated date of transfer (if known), the name and contact information for the intended recipient, and any other information that may seem relevant to the transfer.

Module D: Section 5: Retaining Poliovirus Material

[replace with instructional text

Material to be Retained

	None	Type 1	Type 2	Type 3	Unknown/ Untyped
Infectious Materials	-	-	-	-	-
5.1 WPV or cVDPV	☐	☐	☐	☐	☐
5.2 Sabin/OPV	☐	☐	☐	☐	☐
5.3 Nucleic acid	☐	☐	☐	☐	☐
Potentially Infectious Materials	-	-	-	-	-
5.4 WPV or cVDPV	☐	☐	☐	☐	☐
5.5 Sabin/OPV	☐	☐	☐	☐	☐
5.6 Nucleic acid	☐	☐	☐	☐	☐

5.7 If you plan to retain stored samples, please tell us what types of samples (e.g., fecal specimens, respiratory specimens, nucleic acid) you plan to retain.

MODULE E: KEY FACILITY PERSONNEL

Module E: Section 1: Key Facility Personnel

It is important for us to know who is responsible for the responses provided in the survey. Please include the name and contact information for the individual completing the survey as well as the facility Lab Director and Biosafety Officer.

1. Lab Director Name _____
2. Lab Director Work Email _____
3. Biosafety Officer Name _____
4. Biosafety Officer Work Email _____

☐ Click here if the facility or institution does not have a named Biosafety Officer

MODULE F: ATTESTATION

Please apply a digital signature to confirm the statement below.

☐ I, [*full name of the person completing the survey*], acknowledge that the information provided in this survey is correct to the best of my knowledge and that it reflects the reality of the laboratory, storage site, or other facility type at [*name of parent facility*].

Thank you for completing the U.S. National Poliovirus Containment Survey! Your participation is crucial to the ongoing efforts to contain poliovirus. For more information on polio containment or the national poliovirus containment initiative, please visit our website or email us at poliocontainment@cdc.gov and a member of our staff will follow up with you.

Please encourage others who work with or store the types of materials addressed in this survey to contact the NAC.

Thank you for your commitment to the eradication of polio.

NAC
U.S. National Authority
for Containment of Poliovirus