



Considerations in the framework of Containment of Poliovirus in the Americas, Regional-GAPIII

Aligned with the Regional Plan for Containment of Poliovirus in the Americas, (Regional- GAPIII), and following the recommendations of the Regional Certification Commission (RCC) for Polio Eradication, the Pan American Health Organization proposes the template of **Statement of responsibility for collections of samples with potentially infectious materials (PIM) of OPV2 / Sabin2** (Annex A), where the highest authority of the institution, center, or university declares to have knowledge of the facility retaining poliovirus PIM, the quantity of PIM, and procedure used with PIM; and assumes the responsibilities and commitments of biorisk management in accordance with the materials and laboratory procedures. Any change in the inventory of these PIM or procedures performed in the laboratory must be officially reported to the competent national authority.

The facilities that decide to retain any PIM must sign the declaration of responsibility, and present a letter to national authority (NPCC/NAC) with the rationality to keep these materials.

ANNEX A. STATEMENT OF RESPONSIBILITY FOR COLLECTIONS OF SAMPLES WITH POTENTIALLY INFECTIOUS MATERIALS (PIM) OF OPV2 / SABIN2

COUNTRY: _____

According to the statement in the national survey of poliovirus where the institution, center or university reports the possession of potentially infectious material of OPV2 / Sabin2, this declaration is made to comply with the Regional Plan for the Containment of Poliovirus in the Americas (Regional GAPIII) aligned with the national guides and standards established for this goal.

Name of laboratory or facility	
Full name of the institute, center or university	

Risk classification of OPV/Sabin poliovirus PIM, according type and procedure used with PIM

Type of PV PIM*	Quantity of PIM (e.g. mL, g, o # of vials)	Procedure used with PIM	Risk level
<input type="checkbox"/> Faecal samples <input type="checkbox"/> Concentrated sewage		<input type="checkbox"/> Inoculation into PV-permissive cells	Moderate
		<input type="checkbox"/> Other laboratory procedures**	Low
<input type="checkbox"/> Extracted nucleic acid from faecal samples or concentrated sewage		<input type="checkbox"/> Transfection into PV-permissive cells	Moderate
		<input type="checkbox"/> Other laboratory procedures**	Lowest
<input type="checkbox"/> Respiratory tract samples		<input type="checkbox"/> Inoculation into PV-permissive cells	Low
		<input type="checkbox"/> Other laboratory procedures**	Lowest
<input type="checkbox"/> Extracted nucleic acid from respiratory tract samples		<input type="checkbox"/> Transfection into PV-permissive cells	Low
		<input type="checkbox"/> Other laboratory procedures**	Lowest
<input type="checkbox"/> Inactivated PV PIM***		<input type="checkbox"/> Any	Not PIM

* Cerebrospinal fluid, serum/blood and other clinical materials not listed in this table are not considered PV PIM.
 ** May include, but are not limited to, inoculation into PV non-permissive cells, bacterial cultures, PCRs (DNA or RNA), mass spectrometry or ELISAs.
 *** Must be inactivated using a validated method

The director (or highest authority responsible for the institution) certifies that:

- I. the laboratory where the PIM is stored implements the risk mitigation strategies according to the risk classification for OPV/Sabin poliovirus PIM

- II. any change in the PIM inventory or procedures performed (new or modified techniques) in the laboratory will be officially reported to the competent national authority.

In proof of the veracity of the information and commitment in this declaration, on DD / MM / YY, in the city of _____ sign:

The director (or highest authority of the institution)

Responsible of the laboratory or facility

Printed Name: _____

Printed Name: _____

Position: _____

Position: _____

Signature: _____

Signature: _____

Appendix 1. Risk mitigation strategies for handling OPV/Sabin poliovirus PIM

Risk mitigation strategy	Nivel de riesgo			
	Moderate	Low	Lowest	Storage ² Only
Declare PV PIM in National PV Survey and maintain accurate inventory	✓	✓	✓	✓
Biosecurity (including, for example, locked freezers, limited access, staff training)	✓	✓	✓	✓
Biosafety (including, for example, good laboratory/microbiological practices, and documentation and validation of methods/ standard operating procedures, as described in GAPIII, Annex 6)	✓	✓	✓	n/a
Risk assessment for specific procedures being used	✓	✓	✓	✓
Required polio immunization of staff	✓	✓	n/a ³	n/a
Certification to a national or international standard that includes biosafety and biosecurity components	✓	n/a	n/a	n/a

¹✓: must comply with the risk mitigation strategy; n/a: not applicable.

²For short-term retention only, as determined by the MoH, while the final disposition of the collection is being considered. If “stored” samples are to be handled, the risk mitigation strategies for moderate, low and lowest risk levels must be applied as appropriate for the sample type and procedure

³Recommended