

IMPORTANT NOTICE FROM THE WORLD HEALTH ORGANIZATION (WHO) CONCERNING THE BIOLOGICAL MATERIALS IN THIS SHIPMENT

Please share with the appropriate representative(s) of your institution

Acceptance of the biological materials in this shipment will entail certain obligations under the WHO Pandemic Influenza Preparedness Framework, as detailed below and more fully explained in the Annex to this Notice.

Please note that this Notice is provided at two stages of the process to transfer PIP Biological Materials (PIPBM): 1) in response to a request for PIP BM, as part of the process to assess the request; and 2) as part of the shipping documentation included with the shipment of the PIPBM.

1. Background and Terms

This shipment is made in connection with the “*Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits*” (the “PIP Framework”)¹. The materials contained in this shipment are “**PIP biological materials**” or “**PIPBM**”² and are provided to your institution free of charge³ subject to the following:

a) Agreement to conclude a ‘Standard Material Transfer Agreement 2’ (SMTA 2) with WHO

- Under the PIP Framework, a company, research laboratory or other non-GISRS entity that receives PIPBM from the Global Influenza Surveillance and Response System (GISRS) must conclude a legally binding contract called SMTA 2 with WHO. A model SMTA 2 is found in the PIP Framework at Annex 2.
- By accepting these PIPBM, you recognize that in due course you will be contacted by WHO to discuss and conclude an SMTA 2.
- If you have already concluded an SMTA 2, kindly note that you do not need to sign another one, but please read paragraph b) below, which reflects the decision of the World Health Assembly (WHA) of 24 May 2019.

b) Further transfer of PIPBM and/or use of PIPBM on behalf of another entity

- You may only further transfer the PIPBM in this shipment if the prospective recipient has concluded an SMTA 2 with WHO or you have received authorization to do so from WHO.
- In addition, should you enter into any contract or formal agreement with a manufacturer for the purpose of using PIPBM for commercialization, public use or regulatory approval of that manufacturer’s vaccine, diagnostics, or pharmaceuticals, you will be required to:
 - a. Notify the manufacturer that it will be contacted by WHO to discuss and conclude an SMTA2, if it has not yet concluded one;
 - b. Inform WHO of the use of the PIPBM on behalf of that manufacturer, and provide WHO with the name of said manufacturer by sending an email to piframework@who.int with the subject line: “SMTA 2 Notice”. Please note that WHO only requires you to provide the name of the manufacturer; WHO will then follow up with this manufacturer for purposes of concluding an SMTA 2 with WHO.

¹To download a copy of the PIP Framework, see: [Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits. 2nd edition.](#)

² See PIP Framework Section 4.1 for a full definition of PIPBM.

³ Subject to the availability of funds at the shipping laboratory; the recipient may be requested to bear the shipping costs.

c) Partnership Contribution

- By accepting these PIPBM, you further agree to be contacted by WHO to complete an annual 'Partnership Contribution Questionnaire'.
- The Questionnaire will be used to determine whether or not your institution is an "influenza vaccine, diagnostic [or] pharmaceutical manufacturer" that uses GISRS as provided in the PIP Framework for purposes of the PIP Partnership Contribution. See both section 4.3 and section 6.14.3 of the PIP Framework for more details.

2. Next steps

- **When this Notice is received in response to a request for PIPBM:**
 - If you agree with foregoing, please confirm your request and proceed with receipt of the PIPBM.
 - If you do not agree with foregoing, please cancel your request.
- **When this Notice is received as part of the shipping documentation with the shipment of the PIPBM:**
 - If you agree with the foregoing and the PIPBM are in your possession, there is nothing further to do at this time.
 - If you do not agree with the foregoing, you must arrange for the return of the PIPBM.

If you have any questions regarding this notice, please contact the PIP Framework Secretariat at pipframework@who.int.

Annex

Background information on the *Pandemic Influenza Preparedness Framework* (PIP Framework)

The PIP Framework is an international instrument adopted in May 2011 by the 194 Member States of the WHO. Its objective is to “improve pandemic influenza preparedness and response and strengthen the protection against pandemic influenza by improving and strengthening the WHO Global Influenza Surveillance and Response System (“WHO GISRS”).” This is accomplished through, *inter alia*, the rapid, systematic and timely sharing by countries of their influenza viruses with human pandemic potential with GISRS - which is an international network of public health laboratories specialized in influenza, coordinated by WHO - and the fair and equitable access to vaccines and other benefits arising from such virus sharing with all Member States based on public health risk and need (see PIP Framework, section 1(8) and section 2).

Access to benefits is facilitated principally through two mechanisms: the “Standard Material Transfer Agreement 2” (SMTA2) and the “Partnership Contribution” (PC).

1. **Standard Material Transfer Agreement 2 (SMTA 2)**

The SMTA 2 is a legally binding contract between WHO and any non-GISRS entity, such as a manufacturer, research laboratory or other institution, that receives PIPBM from a laboratory that is part of GISRS. Through this contract, the entity commits to provide to WHO specific products that can be used to prepare for (e.g. training, technology license) or respond to (e.g. vaccines, antivirals, diagnostic kits) pandemic influenza. Each entity, depending on its nature and capacity, will choose from a specific list of benefit sharing options that are described in Annex 2 of the PIP Framework. After an SMTA 2 is concluded, and as long as it remains in force, the entity will be able to receive further shipments of any PIPBM it requests. However, further transfer of PIPBM or use of PIPBM on behalf of another entity are covered by specific provisions of the SMTA 2. See page 1 of this Notice, paragraphs 1&2, for more details. More information of the SMTA 2 is found at: [Standard Material Transfer Agreements \(SMTA2\)](#)

2. **Partnership Contribution (PC)**

The Partnership Contribution, is a “sustainable and innovative financing mechanism” established by WHO Member States under the PIP Framework (see section 6.14 and 6.14.3). The PC is an annual cash contribution to WHO by “influenza vaccine, diagnostic and pharmaceutical manufacturers” (see the definition of this term in PIP Framework section 4.3) that use GISRS. Each year, WHO issues a questionnaire to identify all influenza vaccine, diagnostic and pharmaceutical manufacturers that used GISRS. Receipt of PIPBM constitutes “use of GISRS” and as such, all entities that accept PIPBM will be sent the Questionnaire. Based on the responses to the PC Questionnaire, an entity may be identified as a Contributor to the PIP PC. More information on the PC is found at: [Partnership Contribution](#)

More information on GISRS is found at [Global Influenza Surveillance and Response System \(GISRS\)](#). The full PIP Framework, as well as information and background materials on implementation of the PIP Framework are found at [Pandemic Influenza Preparedness \(PIP\) Framework](#). If you have any questions regarding this notice, please do not hesitate to contact the PIP Framework Secretariat at pipframework@who.int