



**Operational Guidance on Sharing Influenza Viruses with Human
Pandemic Potential (IVPP) under the Pandemic Influenza
Preparedness (PIP) Framework**

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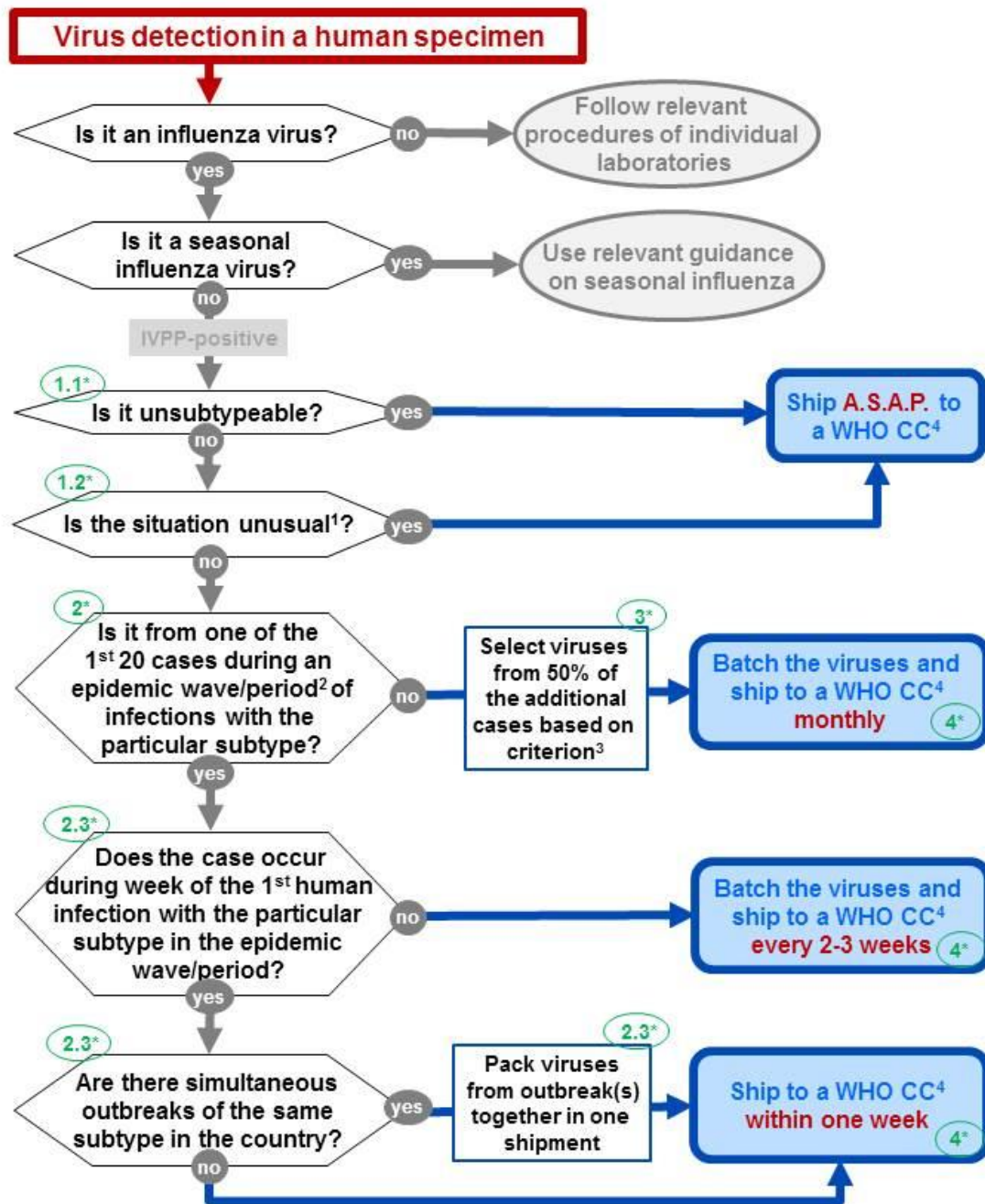
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ABBREVIATIONS

ARI	Acute Respiratory Infections
BM	Biological Materials
CC	Collaborating Centre of GISRS
CDC	Centers for Disease Control and Prevention
Ct	Cycle Threshold
CVV	Candidate Vaccine Virus
ERL	Essential Regulatory Laboratory of GISRS
FAO	Food and Agriculture Organization of the United Nations
GIP	WHO Global Influenza Programme
GISRS	Global Influenza Surveillance and Response System
GSD	Genetic Sequence Data
IHR (2005)	International Health Regulations (2005)
ILI	Influenza-Like Illness
INSDC	International Nucleotide Sequence Database Collaboration
IVPP	Influenza Viruses with Human Pandemic Potential
IVTM	Influenza Virus Traceability Mechanism
MAARI	Medically Attended Acute Respiratory Illness
NIC	National Influenza Centre of GISRS
(PIP) Framework	Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits
RT-PCR	Reverse Transcription Polymerase Chain Reaction
SARI	Severe Acute Respiratory Infection
SMTA 1	Standard Material Transfer Agreement 1
UN	United Nations
VTM	Virus Transport Medium
WHO	World Health Organization

Step-wise Guidance at a Glance

Selection and Shipping of IVPP to WHO CCs of GISRS under PIP Framework



* More information can be found in the corresponding numbered chapters under the section “Guidance on which and when IVPP samples should be shipped to WHO CCs” of the “Operational Guidance on Sharing Influenza Virus of Human Pandemic Potential (IVPP) under the Pandemic Influenza Preparedness (PIP) Framework”.

¹ Unusual situation of IVPP: includes cluster of 3 or more people infected, cluster involving healthcare worker(s) infected, first human infection(s) in a country with a novel subtype which may/may not exist or infect people in other countries, increasing proportion of cases with no known animal contact, and any other situations as advised by WHO.

² Epidemic period: A period of no more than 12 months, e.g. 1 October - 30 September, 1 January - 30 December or another period of 12 months or less depending on seasonal patterns of circulation.

³ Criteria for selection: different age groups, males and females, different geographic locations within the country, different months over the course of outbreak, before and after antiviral treatment, select clinical samples with real-time RT-PCR cycle-threshold (Ct) value of <30.

⁴ WHO CC of the country’s choice (see list: http://www.who.int/influenza/gisrs_laboratory/collaborating_centres/list/)

Purpose

This guidance is intended to help National Influenza Centres (NICs) and H5 Reference Laboratories of the Global Influenza Surveillance and Response System (GISRS) and other Nationally Authorized Laboratories to select and ship IVPP to WHO Collaborating Centres of GISRS under the Pandemic Influenza Preparedness (PIP) Framework.

Background and introduction

In May 2011, the Sixty-fourth World Health Assembly adopted the Pandemic Influenza Preparedness (PIP) Framework for the sharing of influenza viruses with pandemic potential and access to vaccines and other benefits (the “Framework”)¹. Section 5.1.1 of the Framework states that “Member States, through their National Influenza Centres (NICs) and other authorized laboratories, should in a rapid, systematic and timely manner provide PIP biological materials (PIP BM) from all cases of H5N1 and other influenza viruses with human pandemic potential (IVPP)², as feasible, to the WHO Collaborating Centre (WHO CC) or WHO H5 Reference Laboratory of the originating Member State’s choice”.

While this section of the Framework has provided general guidance for the sharing of IVPP, a need was identified by the PIP Review Group³ to develop more precise and specific virus sharing guidance for NICs and other authorized laboratories that identify IVPP during the course of their ongoing surveillance activities. This document operationalizes the general guidance contained in the Framework for WHO Global Influenza Surveillance and Response System (GISRS) laboratories for the rapid sharing and shipment of IVPP. The document will be reviewed and revised periodically based on the characteristics of future IVPP outbreaks and the collective experience gained through its implementation. It also should be noted that this document covers IVPP and is complementary to other WHO guidance that pertains to sharing seasonal influenza viruses and non-IVPP zoonotic influenza viruses, such as those from animal and environmental samples, of public health importance.

Roles of NICs, H5 Reference Laboratories and other authorized laboratories under the PIP Framework

GISRS serves as a global alert and response mechanism for the emergence of influenza viruses, including those with pandemic potential. There are four categories of laboratories

¹ <http://www.who.int/influenza/pip/en/>

² Definition see article 4.2 of PIP FW <http://www.who.int/influenza/pip/en/>

³ http://apps.who.int/gb/ebwaha/pdf_files/EB140/B140_16-en.pdf

within GISRS that have roles related to surveillance and response: NICs, WHO CCs, WHO H5 Reference Laboratories and Essential Regulatory Laboratories (ERLs). Terms of reference related to work with PIP BM for each of these categories of laboratories are elaborated in Annex 5 of the Framework. NICs, which conduct surveillance related to seasonal and pandemic influenza, are designated by their national ministries of health and recognized by WHO. In contrast, H5 Reference Laboratories were designated by WHO on an ad hoc basis since 2004 to support GISRS, especially in countries without reliable laboratory detection capacity in place, in response to the emergence and spread of the highly pathogenic avian influenza viruses of H5N1 subtype. Within this context, a critical role for both NICs and H5 Reference Laboratories is to rapidly share influenza viruses and/or clinical specimens from human infections caused by IVPP with one of the WHO CCs of GISRS: Melbourne (Australia), Beijing (China), Tokyo (Japan), London (United Kingdom of Great Britain and Northern Ireland), Atlanta (United States of America) or Memphis (United States of America). Contact information for WHO CCs is contained in **Annex 1**.

NICs receive clinical specimens collected from patients with influenza-like illness (ILI), severe acute respiratory infections (SARI) or other respiratory syndromes and perform initial detection and identification of influenza viruses, if present. When NICs detect IVPP, they are expected to send IVPP-positive clinical specimens and/or IVPP isolates to WHO CCs. These Centres are responsible for conducting detailed antigenic, genetic and biological characterization of IVPP, and providing critical information for public health risk assessment and risk management, including the development of candidate vaccine viruses (CVVs), and other public health related purposes. Although NICs are encouraged to perform virus isolation for seasonal influenza viruses, they may not have access to appropriate biocontainment facilities or relevant experience of working with highly pathogenic avian influenza viruses such as H5N1, H5N6, H5N8 and other viruses with pandemic potential such as H7N9. Therefore, NICs should not delay shipping influenza virus-positive samples to a WHO CC in pursuit of virus isolation locally. To ensure rapid sharing, it is important that NICs prepare viral materials for shipment as soon as identification has taken place of an unsubtypeable influenza A virus or of an H5, H6, H7, H9, H10 or other non-seasonal influenza viruses including H1 and H3 variant viruses.

Originally, WHO H5 Reference Laboratories were designated to fill in surveillance gaps for countries that did not have the capability to perform laboratory detection of influenza H5N1 viruses. H5 Reference Laboratories and NICs share the same guiding principles and have similar core terms of reference under the Framework (Annex 5 of the Framework) and therefore must share identified IVPP with WHO CCs according to the guidance set out in this document.

The Framework aims to position virus-sharing and benefit-sharing on an equal footing as both are essential for implementing the principles embodied in the Framework. IVPP are

shared through WHO GISRS under the Standard Material Transfer Agreement 1 (SMTA 1) contained in Annex 1 of the Framework. The SMTA 1 is a binding contract that establishes the conditions under which GISRS laboratories exchange PIP BM with each other. Briefly, the NIC or H5 Reference Laboratory sending PIP BM to a WHO CC must:

1. comply with its respective terms of reference as outlined in Annex 5 of the Framework;
2. ensure that materials are handled according to applicable WHO and national biosafety standards;
3. consent to the onward transfer and use of the materials to all members of WHO GISRS according to the terms and conditions specified in SMTA 1;
4. consent to transfer the materials onward to entities outside GISRS, providing that the prospective recipient has concluded or agreed to conclude a Standard Material Transfer Agreement 2 (SMTA 2) with WHO;
5. inform WHO of shipments of materials to entities within and outside GISRS by recording transfer of the PIP BM in the Influenza Virus Traceability Mechanism (IVTM) (Questions regarding how to record the transfer of PIP BM in the IVTM should be addressed to gisrs-whohq@who.int and/or to staff in the WHO CC that will receive the shipment); and
6. comply with requirements of the International Health Regulations (IHR) 2005 according to the procedures established nationally.

Importance of Sharing Influenza Viruses with Pandemic Potential (IVPP)

The rationale for rapidly sharing IVPP-positive clinical specimens and/or IVPP isolates with the WHO CCs is to allow them to conduct required laboratory work:

- to inform public health risk assessments;
- to monitor virus evolution and antiviral susceptibility;
- to determine if current diagnostic tests are working well or if new ones must be developed; and
- to make recommendations on the development of new candidate vaccine viruses (CVVs) at biannual WHO Consultations on the Composition of Influenza Virus Vaccines or during ad hoc assessments.

Guidance on which and when IVPP samples should be shipped to WHO CCs

1. **All** of the following IVPP **must** be shipped to a WHO CC as soon as possible after detection:

- 1.1 All influenza type A virus-positive samples that are **unable to be subtyped** but have virus detected at a concentration that usually allows subtyping (**i.e. with a real-time RT-PCR cycle-threshold (Ct) value of <30**) must be sent to a WHO CC **without delay as soon as shipping paperwork is completed and other relevant arrangements are made**. Viruses present in such samples may be novel and have pandemic potential or indicate that substantial antigenic or genetic changes have occurred in a seasonal virus. It is critical for a WHO CC to carry out detailed characterisation of these viruses as soon as possible.
 - 1.2 In addition, **all** samples from unusual situations⁴ must be sent to a WHO CC **without delay as soon as shipping paperwork is completed and other arrangements are made**. Such situations may indicate a significant change in the epidemiology of IVPP infections that could signal the start of a large outbreak or a pandemic. Because of the potential serious consequences of large outbreaks and pandemics, these particular situations require a virologic investigation by a WHO CC as soon as possible and also may require a special human health and animal health joint investigation by WHO and FAO.
2. In addition to the prompt shipping of the above samples, IVPP-positive clinical specimens and/or IVPP isolates **from each of the first 20 human cases** caused by a **particular subtype** during an epidemic wave or period of infections should be shipped to a WHO CC. The duration of a wave or period to count the first 20 human cases should be no more than 12 months. It can be 1 October–30 September or 1 January–31 December or other time periods depending on seasonal patterns of circulation of the particular subtype IVPP.
 - 2.1 If no sample is left from a particular case for shipping to a WHO CC, the case cannot be counted towards the 20 cases from which samples should be shipped.
 - 2.2 The counting of 20 cases is reset for each epidemic wave or period (no more than a 12-month period) of a particular subtype.
 - 2.3 In instances when there are multiple potential IVPP cases of the same or unknown subtype under investigation simultaneously, it is preferable to batch all IVPP materials obtained within one week in a single shipment. If it is the first shipment of the epidemic wave or period, it should be sent **without delay as soon as shipping paperwork is completed and other relevant arrangements are made**. For subsequent shipments, IVPP materials typically should be batched and shipped every 2 to 3 weeks and at no longer than monthly intervals, unless WHO or the WHO CC receiving the shipment provides different advice.

⁴ 'Unusual situations' include clusters of three or more people infected, clusters involving healthcare worker(s) infected, the first human infection(s) in a country with a novel subtype which may/may not exist or infect people in other countries, an increasing proportion of cases with no known animal contact, and any other situations as advised by WHO.

3. In situations where **more than 20 IVPP cases** caused by a given influenza A subtype are identified in a country over the course of an epidemic wave or period of infections (no more than 12 months), additional criteria should be used by NICs for selecting IVPP materials for shipment to WHO CCs.

- 3.1 After IVPP from the first 20 cases of a given subtype have been shipped to a WHO CC, IVPP from approximately 50% of the additional cases should be selected for shipment and the IVPP materials should be batched for shipment at approximately monthly intervals, or more frequently if advised by WHO or the WHO CC receiving the shipments.

- 3.2 Viruses from family or community clusters, viruses from cases with unusual clinical symptoms (e.g. cases with neurological symptoms), and viruses recommended by WHO or the WHO CC that will receive the shipment should be prioritized.

- 3.3 Otherwise, IVPP should be selected to reflect the proportion of infections in the following:

- different age groups;
- males and females;
- different geographic locations within the country;
- different months over the course of the outbreak; and
- before and after antiviral treatment.

Select clinical specimens whenever possible with a high to moderate viral load (**i.e. with a real-time reverse transcription polymerase chain reaction (RT-PCR) cycle-threshold (Ct) value of <30**), as virus isolation is not often successful when specimens have a high Ct value of >30. Appropriate storage of the specimens within the laboratory (at -70°C or below) and during shipping to a WHO CC (on dry ice) is important as it further increases the likelihood of successful virus isolation. If samples with Ct values of <30 are not available, then the existing IVPP-positive samples should be sent to a WHO CC.

4. If available, both virus isolates and influenza virus-positive clinical specimens for each IVPP should be shipped by NICs to a WHO CC. The reasons for this are:

- 4.1 The provision of virus isolates recovered from fresh clinical specimens increases the likelihood that a WHO CC can culture the virus further. Virus rescue from influenza virus-positive clinical specimens is not always successful, notably when the specimens have been transported, stored and shipped under less-than-ideal conditions.

- 4.2 The provision of influenza virus-positive clinical specimens (approximately 0.5–1.0 ml of clinical specimen) provides the opportunity for a WHO CC to attempt

isolation of viruses in embryonated hens' eggs or in qualified cell lines to obtain viruses that could be used as CVVs.

- 4.3 If the original clinical specimen is the only IVPP material available from a patient, the largest volume possible of this material (approximately 1.0–2.0 ml of clinical specimen) should be shipped, to maximize the likelihood of virus isolation at a WHO CC.
5. If a NIC also serves as a WHO CC, it too must share IVPP materials with other WHO CCs in a timely manner, as outlined in WHO CC core terms of reference B.12 (i) in Annex 5 of the PIP Framework. Viruses that must be shared with other WHO CCs include the following:
 - 5.1 reference viruses for each epidemic wave or period of infections with a duration of no more than 12 months;
 - 5.2 viruses of new subtypes that had not previously infected humans;
 - 5.3 viruses with different genotypes from what had been detected previously;
 - 5.4 viruses with new phenotypes that had not been detected previously (e.g. highly pathogenic viruses of a subtype that was previously shown to be low pathogenic in birds or vice versa, viruses with a greater ability to transmit via aerosols in mammalian model systems and viruses resistant to antivirals without mutations known to confer resistance); and
 - 5.5 other important viruses as discussed with WHO and among WHO CCs.
6. Sharing genetic sequence data (GSD) from IVPP with WHO CCs and submitting GSD to a publically accessible sequence database within a week of obtaining data is very useful for some aspects of public health risk assessment **but does not replace the sharing of biological materials**. Sharing of IVPP materials by NICs and other authorized laboratories is important for comprehensive virologic risk assessment, producing and characterising CVVs, and efforts to maintain virus and benefit-sharing on an equal footing under the WHO PIP Framework.

Shipment of IVPP to WHO CCs

It is important for NICs or other authorized laboratories to contact the WHO CC that will receive the shipment in advance to ensure coordination of shipment details with the required shipping permits. The WHO GIP is able to cover the cost of **four shipments per year**⁵ of seasonal influenza viruses or influenza virus-positive specimens from NICs to a WHO CC. For IVPP sharing, **additional shipments can be supported** by contacting the WHO

⁵ The maximum number of shipments per year is subject to adjustment along the available financial resources.

Global Influenza Programme at gisrs-whohq@who.int or fusterc@who.int, the WHO regional offices or the WHO CCs that will receive the shipment.

For the process of making a shipment see **Annex 2**.

Recording shipments of IVPP in the IVTM

The Influenza Virus Traceability Mechanism (IVTM) is an IT-based system for tracking the transfer and movement of PIP biological materials into, within and out of the WHO GISRS as defined in the Framework. As defined in SMTA 1 in the Annex 1 of the PIP Framework, Providers and Recipients of IVPPs, once a shipment is made or received, are requested to record the shipment and other information of IVPPs in the IVTM.

External factors that may impact the timely sharing of IVPP – share experience with WHO to improve IVPP sharing

Shipping viruses can be complex: it requires, for example, following relevant national and/or international regulations, and obtaining necessary permits and authorizations under local law. This process requires close coordination among many stakeholders, including the shipping and receiving laboratories; ministries of health, trade and/or commerce; transport courier services; airlines; and WHO.

Several external factors can therefore impact a laboratory's capacity to ship viruses. Some of these factors have been listed in the table in **Annex 4**. In order for WHO to better understand the impact of external factors on virus sharing, and with a view to assisting to resolve these barriers, if possible, WHO invites GISRS laboratories who are experiencing, or have experienced, issues with sharing IVPP to share their experience. Information may be sent to pipframework@who.int with the subject line: *Challenges to virus sharing*.

The information you share will be compiled and used to update the table in **Annex 4**. In the future, WHO would like to use this information to assist GISRS laboratories by raising Member States' and stakeholders' awareness of external factors that may impact GISRS laboratories' capacity to share IVPP timely.

General guidance for sharing IVPP and GSD with WHO CCs

- **Any** influenza type A virus that is **unable to be subtyped** but is present at a virus concentration that usually allows subtyping (**i.e. with a real-time RT-PCR Ct value of <30**) should be sent to a WHO CC of GISRS **without delay** after appropriate arrangements for shipping have been made (for details see guidance item 1).
- All IVPP-positive clinical specimens and/or IVPP isolates from cases in unusual situations should be sent to a WHO CC **without delay** after appropriate arrangements for shipping have been made. 'Unusual situations' include clusters of three or more people infected, clusters involving healthcare worker(s) infected, the first human infection(s) in a country with a novel subtype which may/may not exist or infect people in other countries, an increasing proportion of cases with no known animal contact, and any other situations as advised by WHO (for more details see guidance item 1).
- IVPP-positive clinical specimens and/or IVPP isolates **from each of the first 20 human cases** caused by a particular subtype during an epidemic wave or period of infections should be shipped to a WHO CC. The first shipment should take place within the first week after the first case in the epidemic wave or period is detected, and the rest preferably every 2-3 weeks and at no longer than monthly intervals (for details see guidance item 2). The duration of a wave or period to count the first 20 human cases should be no more than 12 months. It can be 1 October–30 September or 1 January–31 December or others depending on seasonal patterns of circulation of the particular subtype IVPP. The count is reset for each epidemic wave or period.
- In situations where **more than 20 human IVPP cases caused by a given subtype** are identified during an epidemic wave or period of infections with a duration of no more than 12 months, IVPP from approximately 50% of additional cases should be selected and shipped monthly using the criteria provided in guidance item 3.
- If available, sufficient volumes of both virus isolates and influenza virus-positive clinical specimens should be shipped to a WHO CC (for details see guidance item 4).
- Regular sharing of IVPP reference viruses and other important viruses among WHO CCs is required as outlined in the WHO CC core terms of reference under the Framework (for details see guidance item 5).
- Genetic sequence data (GSD) from IVPP should be shared with WHO CCs and a publically accessible database such as GISAID or GenBank/International Nucleotide Sequence Database Collaboration (INSDC) within a week of obtaining data. While rapid sharing of GSD from IVPP is very important, sharing of GSD **does not replace** sharing of IVPP materials (for details see guidance item 6).

Annex 1 Contact details for the WHO CCs

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Annex 2 Shipment Processes

World Courier is contracted by WHO through standard processes to transport IVPP isolates or IVPP-positive specimens from NICs, WHO H5 Reference Laboratories and other nationally authorized laboratories to WHO CCs. All designated GISRS laboratories can access WHO funds to support and facilitate the transportation of influenza-positive specimens/virus isolates to WHO CCs. If a laboratory is a NIC, or has no access to World Courier service within their country, they should contact the WHO GIP at gisrs-whohq@who.int or Christian Fuster at fusterc@who.int, or the corresponding WHO regional office.

(i) How to book a shipment

To book a shipment, NICs and other nationally authorized laboratories should contact the receiving WHO CC and complete and submit a booking form to the World Courier Office in Geneva and the WHO GIP (email addresses are listed on the booking form). The booking form is shown in **Annex 3** and can be accessed via the following link: <https://ezcollab.who.int/?lbn7cfn8>, or by contacting WHO GIP at gisrs-whohq@who.int or Christian Fuster at fusterc@who.int. Please complete all required information, including contact information for the person to be contacted for the pick-up, in order to avoid any delay.

A local World Courier agent will contact the NIC or nationally authorized laboratory to arrange collection of the shipment when appropriate import permit(s) and customs documentation are approved. The courier will assist with the consignment note, custom forms and commercial invoice required for shipping. The World Courier agent will also provide all relevant packaging, labelling and dry ice upon request.

NICs should contact the chosen WHO CC to inform them of their intention to ship samples and request the Centre to supply an appropriate import permit. Most WHO CCs have a specific sample submission form to provide virologic, epidemiologic and patient-related information for specimens being shipped. Sample submission forms are available from the chosen WHO CC upon request. Once completed, **the completed sample submission form should be emailed to the chosen WHO CC prior to shipping and accompany the shipment.**

(ii) Sample preparation and packaging

Sample tubes should be clearly labelled using non-erasable ink or printed labels, sent on dry ice and packaged according to international regulations for the transportation of biological

samples (triple packaging system).⁶ The completed sample submission form should be included with the shipment.

Virus isolates and influenza virus-positive specimens should be stored at -70 to -80 °C, which is why they are shipped on dry ice. Shipping or storage of viruses at -20 °C or 2–8 °C will result in degradation of the virus and is not recommended. Where possible, specimens should not have been repeatedly frozen and thawed as this also results in degradation of the virus and will limit the ability of a WHO CC to isolate the virus. It is recommended that 0.5–1.0 ml of Virus Transport Medium (VTM) containing clinical specimen and 1.0–2.0 ml of cell culture-supernatant or hen's egg allantoic fluid containing virus isolate be shipped.

⁶ WHO Guidance on Regulations for the Transport of Infectious Substances: <http://www.who.int/ihr/publications/WHO-WHE-CPI-2017.8/en/>

Annex 3 Booking Form



WHO Influenza Shipment Fund Project

BOOKING FORM **(One form per one shipment)**

PLEASE SEND TO THE WORLD COURIER GENEVA AT THE CONTACT ADDRESS BELOW
BY EMAIL AND/OR FAX TO ARRANGE PICK-UP

!PLEASE FILL IN THIS FORM CAREFULLY!

Information of Booking Form Sending	
Date (dd/mm/yyyy):	
Pages :	
From :	
By :	<input type="checkbox"/> Email <input type="checkbox"/> Fax (please click and cross the box(es) you choose)

TO : World Courier Geneva (Switzerland) SA

Email : opsgva@worldcourier.ch

Fax : + 41-22-827.30.70

CC : World Health Organization
Global Influenza Programme
- Mr. Christian Fuster

Email : gisrs-whohq@who.int

Email : fusterc@who.int

Fax: + 41-22-791.48.78

Requested Date of Pick-up (dd/mm/yyyy) :
--

PERSON TO BE CONTACTED FOR THE PICK-UP :

NAME :	PHONE :
E-MAIL :	

<u>PLACE OF PICK-UP</u>	<u>PLACE OF DELIVERY</u> <small>(please click and cross one box you choose)</small>
Company :	WHO Collaborating Centre in
Street :	<input type="checkbox"/> Atlanta
Dept :	<input type="checkbox"/> Melbourne
City / Zip Code :	<input type="checkbox"/> Tokyo
Country :	<input type="checkbox"/> London
Name :	<input type="checkbox"/> Beijing
Phone :	

Page :1



WHO Influenza Shipment Fund Project

DETAILS OF SHIPMENT :

WHO ACCOUNT : #696002 STUDY / PROTOCOL : WHO

Please click and cross the box(es) you choose:

- BIOLOGICAL SUBSTANCE, CATEGORY B, (UN 3373)¹ [DRY ICE]
- INFECTIOUS SUBSTANCES AFFECTING HUMANS, CATEGORY A, (UN 2814)² [DRY ICE]
- OTHER³: _____

NUMBER OF VIALS AND MLS: _____

NUMBER OF INNER PACKAGING AND SIZE (IF AVAILABLE) : _____

NOTE: LOCAL WORLD COURIER OFFICE OR HIS AGENT WILL PROVIDE DRY ICE, ADEQUATE PACKAGING MATERIALS AND PAPER WORKS (House Air Waybill, DG forms) FOR YOUR SHIPMENT.

KIND REGARDS

¹ This box should be ticked when you are shipping: (diagnostic specimens containing A(H5N1) or diagnostic seasonal influenza A(H3N2), A(H1N1), B specimens or seasonal influenza A(H3N2), A(H1N1), B virus isolates.

² This box should be ticked ONLY when you are shipping virus isolates [Highly pathogenic avian influenza virus (cultures only)] of A(H5N1).

³ This box should be ticked when you are not shipping on the dry ice (-70°C). Please indicate the category (A or B) and temperature conditions: icepacks (0°C to +4°C) or RT-room temperature (18°C to 25°C) or Dry shipper (-210°C to -195°C).

If you are not sure which box to tick, please contact fusterc@who.int BEFORE you send the form.

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Annex 4 External factors that may impact the timely sharing of IVPP

FACTORS	DESCRIPTION	IMPACT ON VIRUS SHARING
National and international regulatory requirements	<ul style="list-style-type: none"> – Multiple national regulations governing export-import of infectious substances, including: <ul style="list-style-type: none"> • Biosafety and biosecurity regulations • Transport regulations • Trade and custom regulations – Implementation of international agreements governing the sharing of virus samples, e.g. the Nagoya Protocol and the Biological Weapons Convention 	<ul style="list-style-type: none"> – Shipping and transport of infectious substances may entail multiple, sometimes complex and time-consuming, administrative processes – Process may involve several ministries (from different sectors) and therefore multiple competent authorities may be responsible for granting authorization to export/import
Political factors	<ul style="list-style-type: none"> – Political nature of decision-making: competing interests and priorities 	<ul style="list-style-type: none"> – Ministries may not prioritize IVPP sharing and therefore may not put in place mechanisms and policies to facilitate timely sharing of IVPP
Motivational factors	<ul style="list-style-type: none"> – Perceived fair and equitable benefit sharing – Acknowledging the contributions of IVPP providers in scientific publication and collaborating with countries and laboratories in research projects 	<ul style="list-style-type: none"> – Without transparency and reciprocity, providers may be more reluctant to share samples
Geopolitical factors	<ul style="list-style-type: none"> – Public health emergencies, natural disasters, complex emergencies, sanctions and embargoes 	<ul style="list-style-type: none"> – Public health emergencies may lead to closed borders, cancelled flights, and other travel and trade restrictions – Other geopolitical factors may also make it difficult to ship samples outside of a country
Technical and economic factors	<ul style="list-style-type: none"> – Lack of trained staff and/or equipment 	<ul style="list-style-type: none"> – There may be insufficient technical resources and trained personnel needed to prepare IVPP samples for shipping