Annex 1

Standard Material Transfer Agreement 1 (SMTA 1)

Standard Material Transfer Agreement within the WHO global influenza surveillance and response system (GISRS)

In furtherance of the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits (the "Framework"), this Standard Material Transfer Agreement ("Agreement" or "SMTA 1") has been developed.

Article 1. Parties to the Agreement

1.1 Parties to SMTA 1 are limited to influenza laboratories that have been designated or recognized by WHO and have accepted to work under agreed WHO terms of reference. In this Agreement:

The Provider is the laboratory sending Materials, as herein defined,

(name and address of the provider or providing institution, designation of the laboratory (i.e. whether NIC/WHO CC/H5RL/ERL/other authorized laboratory), name of authorized official, contact information for authorized official) (hereinafter referred to as "the Provider")[1]

and

The Recipient is the laboratory receiving Materials, as herein defined,

(name and address of the recipient or recipient institution, designation of the laboratory (i.e. whether NIC/WHO CC/H5RL/ERL/other authorized laboratory), name of authorized official, contact information for authorized official) (hereinafter referred to as "the Recipient")[1]

1.2 Provider and Recipient are hereafter collectively referred to as "Parties".

Article 2. Subject matter of the Agreement

PIP biological materials as defined in Section 4.1 of the Framework (hereinafter "Materials") transferred from the Provider to the Recipient are subject to the provisions of this Agreement.

[1] To be completed if signature is required pursuant to Article 11 below.

Article 3. General provisions

The Provider or recipient will consider support to the strengthening of the laboratory and surveillance capacity of the networks of developing countries.

Article 4. Rights and obligations of the Provider

4.1 The Provider undertakes the following with respect to the Materials:

4.1.1. To comply with its respective WHO global influenza surveillance and response system (GISRS) terms of reference.

4.1.2. To ensure that the Materials are handled in accordance with applicable WHO guidelines and national bio-safety standards.[1]

4.2. The Provider agrees to the onward transfer and use of the Materials, to all members of the WHO GISRS, on the same terms and conditions as those provided in Standard Material Transfer Agreement within the WHO GISRS (SMTA 1).

4.3 The Provider consents to the onward transfer and use of the Materials to entities outside the WHO GISRS on the condition that the prospective recipient has concluded a Standard Material Transfer Agreement outside the WHO GISRS (SMTA 2).

4.4 The Provider shall inform the WHO of shipments of Materials to entities inside/outside the WHO GISRS by recording in the Influenza Virus Tracking Mechanism (IVTM).

Article 5. Rights and obligations of the Recipient

5.1 The Recipient undertakes the following with respect to the Materials:

5.1.1 To comply with its respective WHO GISRS terms of reference.

5.1.2. To ensure that the Materials are handled in accordance with applicable WHO guidelines and national bio-safety standards.

5.1.3. To inform WHO of shipments of Materials to entities inside/outside the WHO GISRS by recording in the IVTM.

5.1.4 In the event of further transfers within the WHO GISRS, to do so in accordance with SMTA 1.

5.2 The Recipient shall actively seek the participation of scientists to the fullest extent possible from originating laboratories and other authorized laborato-

[1] *"WHO Guidance on Regulations for the Transport of Infectious Substances"*. Document WHO/CDS/EPR/2007.2. Geneva, World Health Organization 2007 and *"WHO Guidelines for the collection of human specimens for laboratory diagnosis of avian influenza infection"*.

ries, especially those from developing countries, in scientific projects associated with research on clinical specimens and/or influenza virus from their countries and actively engage them in preparation of manuscripts for presentation and publication.

5.3 The Recipient shall appropriately acknowledge in presentations and publications, the contributions of collaborators, including laboratories/countries providing clinical specimens or influenza virus with pandemic potential or reagents, using existing scientific guidelines.

Article 6. Intellectual property rights

6.1 Neither the Provider nor the Recipient should seek to obtain any intellectual property rights (IPRs) on the Materials.

6.2 The Provider and the Recipient acknowledge that any IPRs on the Materials obtained before the date of adoption of the Framework by the World Health Assembly will not be affected by SMTA 1.

6.3 The Provider under SMTA 1 may have used technology protected by IPRs for the generation and/or modification of the Materials. Any recipient of such Materials acknowledges that such IPRs shall be respected.

Article 7. Dispute resolution

7.1 In the event of a dispute under SMTA 1, Parties concerned shall seek in the first instance to settle the dispute through negotiation or any other amicable means of their own choice. Failure to reach agreement shall not absolve the parties to the dispute from the responsibility of continuing to seek to resolve it.

7.2 In the event that the dispute is not settled by the means described under paragraph 1 of this Article, one of the Parties concerned may refer the dispute to the Director-General, who may seek advice of the Advisory Group with a view to settling it. The Director-General may make recommendations to the Parties regarding its resolution and shall report to the World Health Assembly on any such matters.

7.3 The Parties also acknowledge the role of the Director-General under the Framework, in particular under section 7.3.4.

Article 8. Warranty

The Provider makes no warranties as to the safety of the Materials, or as to the accuracy or correctness of any data provided with them. Likewise, the provider does not make any warranties as to the quality, viability, or purity (genetic or mechanical) of the Materials being furnished. The Provider and the Recipient assume full

responsibility for complying with their respective national biosecurity and biosafety regulations and rules as to import, export or release of biological materials.

Article 9. Duration of Agreement

This contractual agreement shall remain in force until December 31, 2021 and shall be automatically renewed until December 31, 2031 unless the World Health Assembly decides otherwise.

Article 10. Acceptance and Applicability

10.1 Recipients or Providers in the WHO GISRS at the time of the adoption of the Framework by the World Health Assembly: Acceptance by such laboratories of their WHO terms of reference, as contained in the Framework, constitutes acceptance of SMTA 1.

10.2 Recipients or Providers that join the WHO GISRS after adoption of the Framework by the World Health Assembly: Acceptance of designation or recognition by WHO to become a WHO GISRS laboratory will constitute acceptance of SMTA 1.

10.3 Applicability: SMTA 1 shall cease to be applicable only upon suspension or revocation of designation or recognition by WHO or upon formal withdrawal by the laboratory of its participation in the WHO GISRS or upon mutual agreement of the WHO and the laboratory. Such a suspension, revocation or withdrawal shall not relieve a laboratory of pre-existing obligations under SMTA 1.

Article 11. Signature

Further to Article 10 above entitled "Acceptance and Applicability", unless either party requires this Agreement to be executed by signature of a printed document, no further evidence of acceptance is required.