14 April 2011 as at 21.40

SMTA 1

Standard Material Transfer Agreement within the WHO Network

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") has been developed. ***(Consensus)***

Article 1. Parties to the Agreement

1.1 Parties to this SMTA are limited to influenza laboratories that have been designated or recognized by WHO and have accepted to work under agreed WHO Terms of Reference.[1] In this Agreement: (*Consensus)*

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")]

and

The Recipient is the laboratory receiving Materials, as herein defined. ***(Consensus)***
[(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. 2 . Provider and Recipient are hereafter collectively referred to as "Parties". ***(Consensus)***

Article 2. Subject Matter of the Agreement

PIP Biological Materials, genetic sequences, [genetic materials,] reference reagents, reference reagents for potency determination of vaccines/vaccine potency reagents, influenza reference viruses, and WHO recommended influenza viruses for vaccine use, **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.**
Or

"PIP biological materials" as defined in the PIP Framework at 4.1.

Or

"PIP biological materials", "genetic materials" and "genetic sequences" as defined in the PIP Framework at 4.1.

Or

Genetic materials, meaning RNA derived from wild-type H5N1 and other human influenza viruses with pandemic potential and cDNA that covers the entire coding region of one or more viral genes.

Article 3. General Provisions

3.1. The Provider or recipient will consider to support the strengthening of the laboratory and surveillance capacity of the networks of developing countries. (*consensus*)

3.2. The parties to this Agreement agree that the World Health Organization is the third party beneficiary under this Agreement.

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 Network Terms of Reference. ***(Consensus)***

4.1.2. To ensure that the Materials are handled in accordance with applicable WHO guidelines and national bio-safety standards.[2] ***(Consensus)***

4.2. The Provider agrees to the onward transfer and use of the Materials, to all members of the WHO Network, on the same terms and conditions as those provided in this SMTA. ***(Consensus)***

4.3 The Provider consents to the onward transfer and use of the Materials to entities outside the WHO Network on the condition that the prospective recipient has concluded, or is in the process of concluding, an SMTA2.

[2] "WHO Guidelines on Regulations for the Transport of Infectious Substances" and "WHO Guidelines for the collection of human specimens for laboratory diagnosis of avian influenza infection."

4.4. The Provider shall inform the WHO of shipments of Materials to entities inside/outside the WHO Network by recording in the IVTM (Consensus)

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 Network Terms of Reference.

5.1.2. To use the PIP Biological **Materials solely for the purposes stated in said Terms of Reference.** Any use of the PIP Biological Materials beyond those purposes will require authorization from the Provider.

5.1.3. To ensure that the Materials are handled in accordance with applicable WHO guidelines and national bio-safety standards. (Consensus)(Footnote secretariat to provide further advice)

5.1.4. To inform WHO of shipments of Materials to entities inside/outside the WHO Network by recording in the IVTM *(Consensus)*

5.1.5 In the event of further transfers within the WHO Network, to do so in accordance with this SMTA. *(Consensus)*

5.2. The Provider shall actively seek the participation of scientists to the fullest extent possible from originating laboratories and other authorized laboratories, 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. (Consensus)

5.3. The Provider 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 on PIP Biological Materials.

6.2 The Provider and the Recipient acknowledge that any intellectual property rights existing as of the date of adoption of the Framework by the World Health Assembly will not be affected by this SMTA.

Article 7. Dispute Resolution

(Note: This text is option 3 provided in the Brazil-led consultations, derived from Article 56 of the IHR (2005))

7.1. In the event of a dispute under this SMTA, Parties concerned shall seek in the first instance to settle the dispute through negotiation or any other peaceful means of their own choice, including good offices, mediation or conciliation. 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, the Parties concerned may agree to refer the dispute to the Advisory Group, which shall consider the matter and may make recommendations to the parties regarding its resolution. The Advisory Group shall report on any such matters in accordance with its regular reporting mandate.

7.3. A Party may at any time declare in writing to the Director-General that it accepts arbitration with regard to all disputes to which it is a party under this SMTA, or with regard to a specific dispute in relation to another Party. A Party may proceed with arbitration if the other Party to the dispute also declares in writing to the Director-General that it accepts arbitration with respect to that dispute. The arbitration shall be conducted in accordance with the Rules of Arbitration of the International Chamber of Commerce. Either Party to the dispute may, if it so chooses, appoint its arbitrator from such list of experts as the Advisory Group may establish for this purpose; both Parties may agree to appoint a sole arbitrator, or presiding arbitrator as the case may be, from such list of experts.

7.4. The Parties that have agreed to accept arbitration shall accept the arbitral award as binding and final.

Article 8. Warranty

The Provider makes no warranties as to the safety of the PIP Biological 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 PIP Biological 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, on the understanding that such regulations and rules shall, at a minimum, meet the relevant WHO standards that are current at the time of acceptance of this Agreement.

Article 9. Duration of Agreement

This Agreement shall remain in force so long as the Framework remains in effect.

Article 10. Acceptance and Applicability

(*Note: This is derived from DG Consultation October 2009*)

10.1. a) Recipients or Providers in the WHO Network 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 this SMTA.

10.1. b) Recipients or Providers that join the WHO Network after adoption of the Framework by the World Health Assembly: Acceptance of designation or recognition by WHO to become a WHO Network laboratory will constitute acceptance of this SMTA.

10.2. Applicability: This SMTA 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 Network [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 this SMTA.

Article 11. Signature

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