Non-Paper 11/05/2010

Draft Standard Material Transfer Agreement

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*

THE PARTIES TO THIS AGREEMENT HEREBY AGREE AS FOLLOWS:

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 *(footnote: other entities may be included as "Parties")*. In this Agreement: (*Consensus)*

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

and

- The Recipient is the laboratory receiving Materials, as herein defined. *(Consensus)*

1.2 Provider and Recipient are hereafter collectively referred to as "Parties". (*Consensus)*

ARTICLE 2 – SUBJECT MATTER OF THE AGREEMENT

2.1 PIP Biological Materials,[[genetic sequences,] [genetic materials,] reference reagents, reference reagents for potency determination of vaccines/vaccine potency reagents, influenza reference viruses, 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.

ARTICLE 3 – RIGHTS AND OBLIGATIONS OF THE PROVIDER

3.1 The Provider will undertake the following with respect to the Materials:

3.1.1 To comply with its respective WHO Network Terms of Reference [and the framework], including [sharing information regarding the material] / [the sharing of viruses and information.]

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

[1] "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."

3.1.3 To comply with the following provision concerning intellectual property rights:

If intellectual property rights are obtained on inventions derived from the use of Materials, the holder/[provider] of such rights should grant to WHO a non-exclusive, royalty-free license, which WHO will sub-license to interested developing countries, for the purpose of maximizing availability of critical benefits on a non-profit basis, such as vaccines and anti-virals, for pandemic influenza preparedness purposes.

Or

[The provider shall not seek to obtain any intellectual property rights in connection with such materials.]

Or

[If the provider is a national government laboratory, it shall not seek to obtain a patent on PIP biological materials transferred pursuant to this SMTA.

The provider and the recipient acknowledge that any intellectual property rights associated with the materials or their use will not be disturbed by this SMTA.]

Or

[Delete]

3.2 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)*

3.3 The Provider consents to the onward transfer [and use] of the Materials to entities outside the WHO Network [on the condition that any such transfer shall be in accordance with SMTA2] **[that any such transfer shall be accompanied by a copy of the attached "Standards terms and conditions for the transfer of Materials".]** [Provider will regularly inform WHO of shipments of Materials to entities outside the WHO Network as recorded in the Influenza Virus Traceability Mechanism.]

And

[Provider will inform WHO of shipments of Materials to entities [inside and] outside the WHO Network as recorded in the Influenza Virus Traceability Mechanism.]

ARTICLE 4 – RIGHTS AND OBLIGATIONS OF THE RECIPIENT

4.1 The Recipient will undertake the following with respect to the Materials:

4.1.1 To comply with its respective WHO Network Terms of Reference [and the Framework], including the sharing of viruses and information.

4.1.2 To ensure that the Materials are handled in accordance with applicable WHO guidelines and national bio-safety standards.[1] *(Consensus) (Footnote, secretariat to provide further advice)*

[4.1.3 The recipient shall record receipt of such material in the WHO IVTM.]

4.1.4 The recipient will consider to support the strengthening of the laboratory and surveillance capacity of the networks of developing countries. *(Consensus)*

4.1.3 To comply with the following provision concerning intellectual property rights:

If intellectual property rights are obtained on inventions derived from the use of Materials, the holder of such rights should grant to WHO a non-exclusive, royalty-free license, which WHO will sub-license to interested developing countries, for the purpose of maximizing availability of critical benefits on a non-profit basis, such as vaccines and anti-virals, for pandemic influenza preparedness purposes.

4.2 As a member of the WHO Network, Recipient recognizes that Materials are provided to facilitate implementation of Recipient's agreed WHO Terms of Reference. Recipient further agrees that the **Materials will be used solely for the purposes stated in said Terms of Reference**. Recipient agrees that any use of the Materials beyond those purposes will require specific authorization from the Provider.

ARTICLE 5 – DISPUTE RESOLUTION

In the event of a dispute under this SMTA, Parties shall first seek an amicable settlement. Should this fail, the dispute may be submitted to the Director-General who will review the circumstances and may consider appropriate action in response to the dispute which may include the suspension or revocation of the WHO designation of the relevant laboratory.[2]

ARTICLE 6 – ACCEPTANCE AND APPLICABILITY

With respect to laboratories 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. Following the adoption of the Framework, designation or recognition by WHO of other laboratories as laboratories in the WHO Network will constitute acceptance of this SMTA by such laboratories. 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. Such a suspension, revocation or withdrawal shall not relieve a laboratory of pre-existing obligations under this SMTA.

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[1] "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."

[2] As provided in Section 7.3.4 of the Framework.

Annex

World Health Organization ("WHO")
Standard Terms and Conditions for Transfers of WHO Pandemic Influenza Preparedness Materials

This document must accompany all shipments of WHO PIP Materials as defined below

The biological materials contained herein shall be referred to as "WHO Pandemic Influenza Preparedness materials" 'or "WHO PIP Materials".

These WHO PIP Materials have been produced through the collaboration of public health laboratories working within the Global Influenza Surveillance Network coordinated by the World Health Organization. These WHO PIP Materials are essential for public health purposes.

The WHO PIP Materials may be used by Recipient subject to the following Standard Terms and Conditions:

1. The WHO PIP Materials contained in this shipment are provided on behalf of the World Health Organization (WHO) as the coordinator of the Global Influenza Surveillance Network.

2. Recipient of the WHO PIP Materials the following shall:

   - Comply with the established charge schedule attached hereto.[1]
   - Apply tiered pricing in pandemic times
   - If intellectual property rights are obtained on inventions derived from the use of WHO PIP Materials, the holder of such rights should grant to WHO a non-exclusive, royalty-free license, which WHO will sub-license to interested developing countries, for the purpose of maximizing availability of critical benefits on non-profit basis, such as vaccines and anti-virals for pandemic influenza preparedness purposes.
   - Consider providing in-kind contributions to global preparedness stockpiles.
   - Provide information to WHO about further transfers of these WHO PIP Materials, including all relevant information regarding the identity of such recipients.
   - Encourage the publication of the results of any research in scientific publications and in the event of publication, to coordinate with WHO to ensure acknowledgment of the contribution of the appropriate WHO Network institutions.
   - Consider providing further benefit sharing on an *ad hoc* basis

3. Neither WHO nor the laboratory shipping the WHO PIP Materials contained herein make any warranties as to the safety of the WHO PIP Materials contained, or as to the accuracy or correctness of any data provided with them. Neither do they make any warranties as to the quality, viability, or purity (genetic or mechanical) of the WHO PIP Materials being furnished. The Recipient assumes full responsibility for complying with its national bio-

[1] Such charge schedule to be developed through appropriate studies and consideration

security and bio-safety 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 the acceptance of the WHO PIP Materials.

4. Any and all further transfers of WHO PIP Materials shall be subject to these Standard Terms and Conditions. The sending laboratory shall clearly mark the materials as "WHO PIP Materials" and include a copy of these Standard Terms and Conditions with any such shipments.

5. Acceptance by Recipient of the WHO PIP Materials contained herein constitutes acceptance of these Standard Terms and Conditions. If a Recipient does not agree to these Standard Terms and Conditions, it shall immediately notify the providing laboratory to arrange their return.

6. Any questions or disputes relating to the interpretation or implementation of these Standard Terms and Conditions shall be brought to the attention of WHO. No public health laboratories working within the Global Influenza Surveillance Network coordinated by the World Health Organization will be subject to dispute settlement actions relating to interpretation or implementation of these Standard Terms and Conditions.

7. Dispute settlement may be initiated by WHO or the Recipient. Any matter relating to the interpretation or application of these Standard Terms and Conditions which is not covered by its terms will be resolved by reference to the laws of Switzerland. Any dispute relating to the interpretation or application of these Standard Terms and Conditions will, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute will be settled by arbitration. The arbitration will be conducted in accordance with the modalities to be agreed upon by the parties, or in the absence of agreement, with the rules of the International Chamber of Commerce. The parties will accept the arbitral decision as final. Any costs associated with dispute settlement shall be shared as assessed by the arbitral panel.

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