Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits

Standard Material Transfer Agreement 2 (SMTA2)

Article 1. Parties to the Agreement

The University of North Carolina at Chapel Hill (hereinafter "the Establishment")
100 Europa Drive, Suite 430
Chapel Hill, NC 27517-4105
USA

and

The World Health Organization (hereinafter "WHO")
20 avenue Appia
1211 Geneva 27
Switzerland

hereinafter together the "Parties" and each a "Party"

Article 2. Subject matter of the Agreement

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

Article 3. Definitions

3.1 As provided for in Section 4 of the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits.

3.2 Other terms as agreed by the parties.

Article 4. Obligations of WHO

WHO will report to the Advisory Group any exceptional transfers of PIP biological materials authorized by the Director-General under Article 5.7 below.

Article 5. Obligations of the Establishment

5.1 The Establishment does not manufacture influenza vaccines, antivirals or products relevant to pandemic influenza preparedness and response.

5.2 The Establishment shall consider contributing to the measures listed below:

- Donations of vaccines;
- Donations of pre-pandemic vaccines;
- Donations of antivirals;
- Donations of medical devices;
- Donations of diagnostic kits;
- Affordable pricing;
- Transfer of technology and processes;
- Granting of sublicenses to WHO;
- Laboratory and surveillance capacity building.

5.3 The Establishment shall inform WHO in writing within 90 days of the entry into force of this SMTA2 that it has duly considered contributing to the measures listed above.

5.4 In the event that one of the measures in 5.2 above is selected, the Establishment shall inform WHO accordingly and, if necessary, the parties shall negotiate a separate agreement in connection therewith.

5.5 The Establishment shall ensure that PIP biological materials are handled in accordance with applicable WHO guidelines and national bio-safety standards.

5.6 If applicable, the Establishment shall appropriately acknowledge in presentations and publications, the contributions of laboratories that are part of the Global Influenza Surveillance and Response System, which are providing PIP biological materials, using existing scientific guidelines.

5.7 The Establishment shall only further transfer the PIP biological materials if the prospective recipient has concluded an SMTA with the World Health Organization. The Establishment shall report any such further transfers to the World Health Organization. The Director-General may, under exceptional circumstances, allow the PIP biological materials to be transferred to a prospective recipient while requesting this aforementioned recipient to enter into an SMTA.

5.8 The Establishment may exchange PIP biological materials with any other holder of an SMTA concluded with the World Health Organization.

Article 6. Dispute resolution

If a dispute cannot be resolved through negotiations or other non-binding means of the parties' choice, disputes shall be subject to non-binding arbitration on conditions that are mutually agreed by the parties.

Any dispute relating to the interpretation or execution of this Agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, and without prejudice to the privileges and immunities enjoyed by WHO, the parties agree to negotiate in good faith to find another means of finally settling the dispute.

Article 7. Liability and indemnity

The Establishment assumes all liability for damages that may arise from its use, storage, transfer, release or disposal of the PIP biological materials. The Establishment agrees that to the extent permitted or authorized under applicable law, it will indemnify and hold harmless WHO from any claims, costs, damages, or expenses arising out of or related to this Agreement or its use of the PIP biological materials, except to the extent those claims, costs, damages, or expenses arise due to the gross negligence or wilful misconduct of WHO employees. In no event will WHO be liable for any special, incidental or consequential damages of any kind in connection with or arising out of this agreement, or the Establishment's use of the PIP biological materials.

Article 8. Privileges and Immunities

Nothing in or relating to these clauses shall imply the obligation of WHO to submit to any national legislation or jurisdiction, or be deemed a waiver of any of the privileges and immunities of WHO in conformity with the Convention on the Privileges and Immunities of the Specialized Agencies approved by the General Assembly of the United Nations on November 21, 1947 or otherwise under any national or international law, convention or agreement.

Article 9. Use of Name and/or Emblem

Except as otherwise explicitly provided in this Agreement, neither Party shall, in any statement or material of an advertising or promotional nature, refer to the relationship of the Parties under this Agreement, or otherwise use the other Party's name, acronym and/or emblem, without the prior written consent of that other Party.

Article 10. Warranties

WHO 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, WHO does not make any warranties as to the quality, viability, or purity (genetic or mechanical) of the PIP biological materials being furnished. The Establishment assumes full responsibility for complying with its national bio-security and bio-safety regulations and rules as to import, export or release of biological materials.

Article 11. Entry into Force and Duration of Agreement

11.1 This agreement shall enter into force upon the date it has been signed by both parties. It shall remain in force as long as the Establishment does not manufacture influenza vaccines, antivirals or products relevant to pandemic influenza preparedness and response or until 31 December 2031, whichever comes first, or unless terminated pursuant to paragraph 12.1 herein.

11.2 In the event that the Establishment begins manufacturing influenza vaccines, antivirals or products relevant to pandemic influenza preparedness and response, paragraph 12.2 shall apply.

Article 12. Termination

12.1 This agreement may be terminated by either party with three months written notice.

12.2 This Agreement shall automatically terminate if the Establishment begins manufacturing influenza vaccines, antivirals or products relevant to pandemic influenza preparedness and response. In such case, the Establishment shall immediately inform WHO and cease any and all use of PIP biological materials unless and until a new SMTA2 is concluded between the Parties.

12.3 Upon termination, the Establishment shall return to the provider or destroy (as advised by the provider) any PIP biological materials.

Article 13. Signature and Acceptance

In WITNESS Whereof, this Agreement has been duly executed by the Parties.

SIGNED for and on behalf of WHO

Signature

Name: Dr. Keiji Fukuda

Title: Assistant Director-General for Health Security

Date: 2 Oct 2015

SIGNED for and on behalf of the Establishment

Signature

Name: Jacqueline Quay, JD

Title: Director of Licensing Office of Technology Development

Date: 9/16/15

The Terms of this agreement have been read and acknowledged by the Establishment's researcher using the PIP Biological Materials:

Signature

Name: Dr. Sam Lai
Title: Assistant Professor
Date: 9/16/2015