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

Santé Québec (hereinafter "CHU"), legal person established in the public interest constituted under an *Act respecting the governance of the health and social services system*, (CQLR c. G-1.021), acting through its institution **CHU de Québec - Université Laval**, located at 11 Côte du Palais, Québec, Québec G1R 2J6, Canada, represented for the purposes hereof by Mr. Martin Beaumont, President and Executive Director and Serge Rivest, PhD, Director of Research, duly authorized in accordance with Santé Québec's by-laws;

and

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

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

and to which intervenes:

Université Laval (hereinafter the "University"), a university having its headquarters at 2320, rue des Bibliothèques, Québec, Québec G1V 0A6 Canada, it being understood that CHU is duly affiliated to University by way of agreement that provides for, among other terms and conditions, the management by University of institutional intellectual property rights for their mutual benefit and interest.

The CHU and University shall be referred to together as the "Establishment".

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 Agreement 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.

5.9 In the event that the Establishment enters into any contract or formal agreement with a manufacturer for the purpose of using PIP biological materials for commercialization, public use or regulatory approval of that manufacturer's vaccine, diagnostics, or pharmaceuticals, the Establishment shall:

- Inform the manufacturer that it will be contacted by WHO to discuss conclusion of an SMTA 2 (if one is not already concluded); and

- Inform WHO of the use of the PIP biological materials on behalf of that manufacturer and provide WHO with the name of said manufacturer by sending an email to pipframework@who.int with the subject line: "SMTA 2 Notice".

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 binding arbitration on conditions that are mutually agreed by the Parties.

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. To the extent permitted or authorized under applicable law, the Establishment agrees that it will indemnify and hold harmless WHO from any claims, costs, damages, or expenses arising out of or related to this Agreement or the PIP biological materials made by the Establishment, or made against WHO by any other party. 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 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, unless terminated under Article 12.

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. Governing law

Any matter relating to the interpretation or application of this Agreement which is not covered by its terms will be resolved in accordance with general principles of international law.

Article 14. Signature and Acceptance

This Agreement may be executed in one or more counterparts, each of which shall be an original, and all of which together shall constitute a single instrument. Further, the Parties agree that this Agreement may be signed and/or transmitted by electronic mail of a .PDF document or electronic signature (e.g., DocuSign or similar electronic signature technology) and thereafter maintained in electronic form, and that such electronic record shall be valid and effective to bind the Party so signing as a paper copy bearing such Party's hand-written signature. The Parties further consent and agree that the electronic signatures appearing on this Agreement shall be treated, for purpose of validity, enforceability and admissibility, the same as hand-written signatures.

Article 15. Language

The Establishment notes for reference and for its internal purposes that in accordance with the Québec's Charter of the French Language, RLRQ. c. C-11, this Agreement can be written in the English language only. *En conformité avec les dispositions de la Charte de la langue française, RLRQ. c. C-11 du Québec, ce contrat peut être rédigé en anglais uniquement.*

Article 16. Notices

Any notices required to be given or which shall be given under this Agreement shall be delivered by recognized overnight courier service, personal delivery, by certified or registered mail (with return receipt requested) or by email, addressed to the Parties as shown below, and shall be deemed to have been given or made as of the date received, except that notices given by email shall be deemed to be received at the time of transmission. Where transmission occurs outside business hours of the recipient, receipt shall be deemed to take place when business hours of the recipient resume.

If to WHO:

PIP Framework Secretariat
The World Health Organization
20 avenue Appia, 1211
Geneva 27, Switzerland

pipframework@who.int

If to CHU:

CHU de Québec – Université de Laval
Research Centre
Contracts Office
2705 Laurier Boulevard, Suite TR-72
Québec, Québec G1V 4G2 Canada
T: +1 418 525 4444, etc. 46165
bureaudescontrats@crchudequebec.ulaval.ca

If to University:

Community - University Liaison Office
Vice Rectorate Research and Innovation
Université Laval – Pavillon Jeanne-Lapointe
2320, rue des Bibliothèques, room 1454
Québec (Québec) G1V 0A6 Canada
Email : blum@vrr.ulaval.ca

With a copy to

Guy Boivin, MD, FRCPC
Researcher
CHU de Québec-Université Laval
Pavilion CHUL
2705 Laurier Boulevard, Suite R-0709
Québec, Québec G1V 4G2 Canada
Tél.: (418) 525-4444, poste 47762 / 48907
(418) 654-2715
guy.boivin@crchudequebec.ulaval.ca

(signature page follows)

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

SIGNED for and on behalf of WHO

Signature

Name: Dr Michael J. Ryan
Title: Executive Director
WHO Health Emergencies Programme
And Deputy Director-General

Date:

24 JAN 2025

SIGNED for and on behalf of the CHU de Québec – Université Laval

Martin Beaumont

Signé électroniquement par : Martin Beaumont
Motif : J'approuve ce document. / I approve this document
Date : 14 janv. 2025 08:24 EST

Signature

Name: Martin Beaumont
Title: President and Executive Director

Date: 14 janv. 2025

SR

Signé électroniquement par : Serge Rivest
Motif : J'approuve ce document. / I approve this document
Date : 8 janv. 2025 11:46 EST

Signature

Name: Serge Rivest, PhD
Title: Director of Research

Date: 8 janv. 2025

SIGNED for and on behalf of the Université Laval

Signature

Name: Eugénie Brouillet
Title: Vice-Rector for Research and Innovation

Date: 2025-01-15

The Terms of this Agreement have been read and acknowledged by the researcher using the PIP Biological Materials:

GB

Signé électroniquement par : GB
Motif : J'approuve ce document. / I approve this document
Date : 8 janv. 2025 09:21 EST

Signature

Name: Dr. Guy Boivin
Title: Researcher

Date: 8 janv. 2025