

Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits

Report by the Director-General

The Director-General has the honour to transmit to the Executive Board the report of the Open-Ended Working Group of Member States on Pandemic Influenza Preparedness: sharing of influenza viruses and access to vaccines and other benefits, reflecting the outcome of its deliberations in December 2010 (see Annex).

ANNEX

**REPORT OF THE OPEN-ENDED WORKING GROUP OF MEMBER STATES ON
PANDEMIC INFLUENZA PREPAREDNESS: SHARING OF INFLUENZA
VIRUSES AND ACCESS TO VACCINES AND OTHER BENEFITS**

1. The Open-Ended Working Group of Member States on Pandemic Influenza Preparedness: sharing of influenza viruses and access to vaccines and other benefits reconvened in Geneva from 13 to 17 December 2010 and was co-chaired by Ambassador J. Gomez-Camacho (Mexico) and Ambassador B. Angell-Hansen (Norway), with the following vice-chairs: Mr Faiyaz Kazi (Bangladesh), Ms. Joanne Hamilton (Canada), Dr Mokhtar Warida (Egypt), Dr Masato Mugitani (Japan), Ms Jo Newstead (United Kingdom of Great Britain and Northern Ireland) and Mrs Petronellar Nyagura (Zimbabwe). The session was attended by 84 Member States and one regional economic integration organization.
2. The Open-Ended Working Group discussed the preliminary findings of the technical studies undertaken in accordance with resolution WHA63.1, which focused on four areas where Member States had indicated that further information was needed:¹ laboratory and surveillance capacity building, including that required under the International Health Regulations (2005); expanding influenza vaccines production capacity including under the Global Action Plan to Increase Supply of Pandemic Influenza Vaccines; increasing access, affordability and effective deployment of vaccines, antiviral agents, diagnostics and other materials for pandemic preparedness and response; and possible sustainable financing and solidarity mechanisms and other approaches to address the needs identified.
3. The Open-Ended Working Group engaged in constructive discussions and negotiations on the Pandemic Influenza Preparedness Framework and Standard Material Transfer Agreements (SMTA) for entities inside the WHO network, as well as a proposed Standard Terms and Conditions (STC)/SMTA for entities outside the WHO network. There seems to be an emerging consensus that WHO should play a leading role in a global pandemic influenza preparedness benefit sharing system.
4. In order to finalize the Framework on Pandemic Influenza Preparedness on the sharing of influenza viruses and access to vaccines and other benefits, including its annexes, the Working Group proposes to resume from 11 to 15 April 2011.
5. The Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits and its annexes (documents A62/5 Add.1 and A63/48), as amended (see appendices 1 and 2), reflect the discussions and proposals of the Working Group and will be the bases for continued work.
6. Agreement was reached on a number of issues, including:
 - (a) The need to finalize the Framework for Pandemic Influenza Preparedness including its annexes.

¹ See paragraph 7 of A63/48.

- (b) The implementation of multiple tools, interlinked as necessary, are needed to address the set of challenges associated with achieving pandemic influenza preparedness and response including, *inter alia*, as outlined in a preliminary way in the draft technical study. These may include: separate, but complementary instruments for relevant materials, such as an SMTA within the WHO network, and an STC/SMTA for transfers outside the WHO network; strengthening all measures to increase global pandemic influenza vaccine supply, including through support for WHO's Global Pandemic Influenza Action Plan to Increase Vaccine Supply (GAP), and laboratory and surveillance capacity building including that required under the International Health Regulations (2005).
- (c) The need for multiple sources of financing to address these challenges in the short-, medium-, and long-term, including strengthening existing sources/mechanisms of finance and examining the need for new sustainable/innovative financing mechanisms for the Pandemic influenza preparedness (PIP) benefit sharing system.
- (d) To hold, during the intersession, consultations by the co-chairs with civil society, which will be open to all Member States and regional economic integration organizations. They will also hold consultations with industry representatives and with other key stakeholders, including scientific institutions, from developed and developing countries. The co-chairs will report back to the Open-Ended Working Group on their consultations, including through the Bureau meetings. The co-chairs will continue with informal consultations with Member States and regional economic integration organizations during the intersession.
- (e) To hold informal consultations during the intersession, including through electronic means, which will be organized by the following Member States and on the following subject matter, respectively: Australia on the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity; Brazil on dispute resolution (SMTA inside the system); and India on definitions and use of terms. The Bureau will facilitate regional participation in the aforementioned consultations.
- (f) Requests the Director-General to seek information from WIPO on PIP- related patents, including patent applications, in connection with the H5N1 virus and the pandemic (H1N1) 2009. Countries are invited to help with the patent research on this matter.
- (g) To submit the report of the Open-Ended Working Group, the Framework and its annexes, as amended, through the Director-General to the Executive Board at its 128th session.
- (h) To inform deliberations at the April 2011 meeting, the Director-General will finalize the report of the technical studies prepared in accordance with resolution WHA63.1, including a realistic assessment of short-, medium-, and long-term needs for pandemic influenza preparedness and response, and possible sources/mechanisms of financing, including existing sources/mechanisms, for each set of needs.

APPENDIX 1

Appendix 1 contains the text of document A62/5/Add.1, Appendix, originally presented to the Sixty-second World Health Assembly, **as amended** by the Open-Ended Working Group of Member States on Pandemic Influenza Preparedness: sharing of influenza viruses and access to vaccines and other benefits at its meeting in Geneva from 13 to 17 December 2010.

**PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK¹
FOR THE SHARING OF INFLUENZA VIRUSES AND
ACCESS TO VACCINES AND OTHER BENEFITS**

	Page
1. PRINCIPLES	8
2. OBJECTIVE	10
3. SCOPE	11
4. DEFINITIONS AND USE OF TERMS	
4.1 Scientific terms.....	11
4.2 Institutions, organizations and entities.....	12
4.3 Other terms.....	13
5. PANDEMIC INFLUENZA PREPAREDNESS SYSTEM FOR SHARING OF H5N1 AND OTHER INFLUENZA VIRUSES WITH HUMAN PANDEMIC POTENTIAL	
5.1 General.....	14
5.2 Genetic sequence data.....	16
5.3 Traceability and reporting mechanisms	16
5.4 Standard Material Transfer Agreement.....	17
General	17
Execution of the Standard Material Transfer Agreement	17
6. PANDEMIC INFLUENZA PREPAREDNESS BENEFIT SHARING SYSTEM	
6.1 General.....	17
6.2 Pandemic risk assessment and risk response	18
6.3 Provision of PIP Candidate Vaccine Viruses.....	19
6.4 Provision of diagnostic reagents and test kits	19
6.5 Provision of reference reagents for potency determination of vaccines	19
6.6 Laboratory and influenza surveillance capacity building	19
6.7 Regulatory capacity building	20
6.8 Antivirals stockpiles.....	20
6.9 Pandemic influenza preparedness vaccine stockpile.....	20

¹ A proposal has been made for the use of the term “Guidelines” in place of “Framework” throughout this text. Proposals have also been made for the use of the terms “Multilateral Framework” or “International Framework” and/or “Global sharing”.

6.10	Access to vaccines in the interpandemic period for developing countries	21
6.11	Access to pandemic influenza vaccines.....	21
6.12	Tiered pricing	22
6.13	Technology transfer.....	22
6.14	Sustainable and innovative financing mechanisms	22
7.	GOVERNANCE AND REVIEW	
7.1	General.....	23
7.2	Advisory Group	24
7.3	Governance and Review of Terms of Reference for [WHO Network] Laboratories .	24
7.5	Review of Framework	25

ATTACHMENTS

Attachment 1	Standard Material Transfer Agreement	26
Attachment 2	Advisory Group Terms of Reference	36
Attachment 3	WHO Collaborating Centres for Influenza Terms of Reference related to work with Pandemic influenza preparedness biological materials.....	38
Attachment 4	Guiding Principles for the development of Terms of Reference for current and potential future [WHO Network] Laboratories for H5N1 and other human pandemic influenza viruses	55

Proposed preambular paragraphs

[Noting there has been a breakdown of trust in a global influenza surveillance network and the network does not deliver the desired level of transparency, fairness and equity]

1. PRINCIPLES

[That the threat of pandemic influenza persists. Timely sharing of surveillance information and highly pathogenic avian influenza viruses, as well as ensuring equitable access to effective vaccinations, medicines and related technology are important ingredients of global readiness to respond to the pandemic. The Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits is an international mechanism to implement a fairer, more transparent, equitable and efficient system. In developing countries, support to implementation of national integrated human and animal influenza action plans and building national minimum core capacity for detection, risk assessment, laboratory confirmation and rapid containment are critical success factors.]

1.1 In relation to Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits, WHO Member States:

(PP1) Recall World Health Assembly resolution WHA60.28 on Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits; (*Consensus*)

(PP2) Note the continuing risk of an influenza pandemic with potentially devastating health, economic and social impacts, particularly for developing countries which suffer a higher disease burden and are more vulnerable; (*Consensus*)

(PP3) Recognize that Member States have a commitment to share on an equal footing H5N1 and other influenza viruses of human pandemic potential and the benefits, considering these as equally important parts of the collective action for global public health; (*Consensus*)

(PP4) This Framework will be guided by the goal of its universal application for the protection of all people of the world from the international spread of disease; (*Consensus*)

(PP5) Recall the need for rapid, systematic and timely sharing of H5N1 and other influenza viruses with human pandemic potential with WHO Collaborating Centres on Influenza and WHO H5 Reference Laboratories as a contribution to assessment of pandemic risk, development of pandemic vaccines, updating of diagnostic reagents and test kits, and surveillance for resistance to antiviral medicines; (*Consensus*)

(PP6) Reaffirm obligations of States Parties under the International Health Regulations (2005);¹ (*Consensus*)

(PP7) Recognize this Framework is to be implemented in a manner consistent with applicable national and international laws, regulations, and obligations; (*Consensus*)

¹ See <http://www.who.int/csr/ihr/en/>.

(PP8) Recognize that the benefits arising from the sharing of H5N1 and other influenza viruses with human pandemic potential should be shared with all Member States based on public health risk and need; (*Consensus*)

(PP9) Recognize the need for a fair, transparent, equitable and efficient framework for the sharing of H5N1 and other influenza viruses with human pandemic potential and for the sharing of benefits, including access to and distribution of affordable diagnostics and treatments, including vaccines, to those in need, especially in developing countries, in a timely manner; (*Consensus*)

(PP10) Recognize also the WHO leadership and oversight functions over these issues and the need for collaboration with United Nations System Influenza Coordinator and relevant intergovernmental organizations; (*Consensus*)

(PP11) Recognizing the sovereign right of States over their biological resources and the importance of collective action to mitigate public health risks; (*Consensus*)

[(PP12) [Recognizing articles 3bis* and 6(b)* of the Nagoya Access and Benefit Sharing Protocol to the Convention on Biological Diversity;]

[*Footnote: to be updated when the Nagoya protocol text is edited]

Or

[Recognizing that influenza pathogens do not fall within the scope of the Convention on Biological Diversity or the Nagoya Protocol]

[(PP13) [Recognize]/[Recall] the Doha Declaration on the TRIPS Agreement and Public Health as well as the Global strategy on public health, innovation and intellectual property, adopted in resolution WHA61.21.];

Or

[Recalling the Global Strategy on Public Health, Innovation and Intellectual Property, adopted in resolution WHA61.21]

Or

[Delete]

(PP14) Recall that resolutions WHA60.28 and WHA61.21 recognize that “intellectual property rights do not and should not prevent Member States from taking measures to protect public health” and “that intellectual property rights are an important incentive in the development of new health care products. However, this incentive alone does not meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain”; (*Consensus*)

(PP15) Recognize that the commitment to share on an equal footing H5N1 and other influenza viruses of human pandemic potential and the benefits enables WHO Member States and the Director-General to assess the global risk of an influenza pandemic and allows WHO Member States and the

Director-General to take actions to reduce the risk of the emergence of a pandemic and to facilitate the development and production of vaccines, diagnostic materials and other pharmaceuticals that can assist in rapidly responding to and containing an emerging pandemic; (*Consensus*)

(PP16) Acknowledge with serious concern that current global influenza vaccine production capacity remains insufficient to meet anticipated need in a pandemic; (*Consensus*)

(PP17) Acknowledge with serious concern that the distribution of influenza vaccine manufacturing facilities is inadequate particularly in developing countries and that some Member States can neither develop, produce, afford nor access the vaccines and other benefits; (*Consensus*)

(PP18) Note the WHO Global pandemic influenza action plan to increase vaccine supply (GAP)¹ and its goal of reducing the gap between potential vaccine demand and supply during an influenza pandemic, by expanding the global capacity to produce influenza vaccine, including in developing countries; (*Consensus*)

(PP19) Recognize the importance of Member States, pharmaceutical manufacturers and other entities with access to relevant technologies in respect of influenza vaccine, diagnostics, and pharmaceuticals making specific efforts to transfer these technologies, skills, knowledge and know-how to countries, particularly developing countries, that do not currently have access to these technologies, skills, knowledge and know-how; (*Consensus*)

(PP 20) Recognize the need for financing mechanisms that would promote affordability and equitable access to quality influenza vaccines, medicines and technologies by developing countries. (*Consensus*)

2. OBJECTIVE

2.1 The objective of the Pandemic Influenza Preparedness Framework is to improve pandemic influenza preparedness and response, and strengthen the protection against the pandemic influenza by improving and strengthening the [WHO global influenza surveillance and response system] / [WHO influenza surveillance and response system (WISRS)], with the objective of a fair, transparent, equitable, efficient, effective system for [, on an equal footing:]

- (i) the sharing of H5N1 and other influenza viruses with human pandemic potential; and
- (ii) Access to vaccines and [sharing of] other benefits.

¹ Document WHO/CDS/EPR/GIP/2006.1;
http://www.who.int/csr/resources/publications/influenza/CDS_EPR_GIP_2006_1.pdf.

3. SCOPE

3.1 This Framework applies to the sharing of H5N1 and other influenza viruses with human pandemic potential and the sharing of benefits. (*Consensus*)

3.2 This Framework does not apply to seasonal influenza viruses or other non-influenza pathogens or biological substances that may be contained in clinical specimens shared under this Framework. (*Consensus*)

4. DEFINITIONS AND USE OF TERMS

(On the good faith understanding that all uses of the term “influenza virus” are understood to refer to “H5N1 and other influenza viruses with human pandemic potential”).

For the purpose of this Framework, the following terms have the meanings assigned to them below. (*Consensus*)

4.1 Scientific terms

Pandemic Influenza Preparedness Biological Materials or PIP Biological materials

“PIP biological materials”, for the purposes of this Framework (and its annexed SMTA and TORs) and the Influenza Virus Tracking Mechanism (IVTM), includes human clinical specimens,¹ virus isolates of wild type human H5N1 and other influenza viruses with human pandemic potential; and modified viruses prepared from H5N1 and/or other influenza viruses with human pandemic potential developed by [WHO [Network Influenza][GISN] laboratories], these being candidate vaccine viruses generated by reverse genetics and/or high growth re-assortment. (*Consensus*)

[Genetic materials, specifically RNA and cDNA, derived from wild-type H5N1 and other human influenza viruses with human pandemic potential.]

“Genetic sequences” means the order of nucleotides found in a molecule of DNA or RNA. They contain the genetic information that determines the biological characteristics of an organism or a virus. (*Consensus*)

“Reference reagents” are biological or chemical substances or organisms and parts thereof used in diagnostic or surveillance activities. They are rigorously characterized and shown to be suitable for use as standards in order to compare and validate results of analyses obtained in different laboratories. (*Consensus*)

“Reference reagents for potency determination of vaccines/vaccine potency reagents” means reagents used by vaccine manufacturers and regulatory laboratories for the purpose of testing and standardizing the potency of vaccines against H5N1 and other influenza viruses with human pandemic potential. (*Consensus*)

¹ The definition for this term has been provided.

“Influenza virus with human pandemic potential” designates any wild-type influenza virus that has been found to infect humans and that has a haemagglutinin antigen that is distinct from those in seasonal influenza viruses so as to indicate that the virus has potential to be associated with pandemic spread within human populations with reference to the International Health Regulations (2005) for defining characteristics. (*Consensus*)

“Pandemic Influenza Preparedness vaccine virus” or “PIP vaccine virus” connotes any high-growth reassortant virus or any influenza reference virus, WHO-recommended influenza virus for vaccine use or other influenza virus material generated, including by new and emerging technologies, from H5N1 or other influenza virus with human pandemic potential that is provided to influenza vaccine manufacturers for the purposes of developing a prototype pandemic, pre-pandemic, pandemic or other influenza vaccine. (*Consensus*)

“Clinical specimens” means materials taken from [humans or animals, in as far as the samples taken from animals are shared by originating countries] laboratories with [the WHO Network]] [the respiratory tract (for example, swabs and aspirated fluid), and also blood, serum, plasma, feces, and tissues, collected from humans/[and non-human sources/animals] for diagnostic purposes [, detection of pathogens and further characterization], study or analysis.

“High-growth reassortant influenza viruses” means hybrid influenza viruses, including recombinant viruses, that have been generated from two or more different influenza viruses and selected to grow better in eggs or tissue cultures for optimal influenza vaccine production. (*Consensus*)

“Influenza reference viruses” means wild-type influenza viruses of human or animal origin that WHO has selected as representative of important groups of influenza viruses on the basis of extensive antigenic and genetic studies and comparisons with influenza viruses from many countries. As the influenza viruses evolve in nature, new influenza reference viruses are selected. (*Consensus*)

“WHO-recommended influenza viruses for vaccine use” means wild-type influenza viruses that are recommended by WHO as the basis for an influenza vaccine. (*Consensus*)

“Wild-type influenza viruses or influenza virus isolates” means naturally occurring influenza viruses that have been detected by any means including molecular methodology and/or cultured either in eggs or cells (i.e. isolated) directly from clinical specimens or subsequent culture passages and have not been purposefully modified. (*Consensus*)

4.2 Institutions, organizations and entities

“Essential regulatory laboratories” means influenza laboratories designated by WHO located in, or associated with, national regulatory agencies and which have a critical role at the global level for developing, regulating and standardizing human influenza vaccines. Such laboratories participate in the [WHO Network] in accordance with their corresponding terms of reference. (*Consensus*)

“Influenza vaccine, diagnostic and pharmaceutical manufacturers” means public or private entities including academic institutions, government owned or government subsidized entities, nonprofit organizations or commercial entities that develop and/or produce human influenza vaccines and other products derived from or using H5N1 or other influenza viruses of human pandemic potential. (*Consensus*)

“National Influenza Centres” or “NICs” means influenza laboratories authorized and designated by the Member State and subsequently recognized by WHO to perform a number of functions including providing PIP biological materials to the [WHO Network] in accordance with the Terms of Reference. *(Consensus)*

“Other authorized laboratory” means influenza laboratories authorized by the Member State to provide PIP biological materials to the [WHO Network]. This term is intended to cover laboratories in those Member States which do not have a National Influenza Centre or Member States with NICs but which also have additional laboratories with certain roles usually performed by NICs. *(Consensus)*

“Public health researchers” means researchers in public health and/or basic sciences at public or private institutions outside of the [WHO Network], universities and other academic research institutions with a primary research interest in public health. *(Consensus)*

“WHO Collaborating Centres on Influenza” or “WHO CCs” means influenza laboratories designated by WHO and supported by national authorities to perform certain roles within the [WHO Network], and which have accepted formal Terms of Reference from WHO. In general, they differ from National Influenza Centres and WHO H5 Reference Laboratories in having global responsibilities and more extensive technical capacities. *(Consensus)*

“WHO H5 Reference Laboratories” means influenza laboratories that have been designated by WHO in order to strengthen national and regional capacity for reliably diagnosing H5 virus infection until this capacity is more widespread. *(Consensus)*

[“WHO Network”] means the international network of influenza laboratories, coordinated by WHO, that conduct year-round surveillance of influenza, assessing the risk of pandemic influenza and assisting in preparedness measures. The [WHO Network] comprises National Influenza Centres, WHO Collaborating Centres on Influenza, WHO H5 Reference Laboratories and Essential Regulatory Laboratories. *(Consensus)*

4.3 Other terms

“Advisory Group” means the Group referred to in paragraph 7.2 of this Framework. *(Consensus)*

“Affected country” means countries with laboratory confirmed cases of H5N1, or other influenza viruses with human pandemic potential. *(Consensus)*

“Director-General” means the Director-General of the World Health Organization. *(Consensus)*

“Least-developed country” means those countries that are periodically classified as least-developed countries by the United Nations Committee for Development Policy. *(Consensus)*

“Originating laboratory” means a National Influenza Centre or other authorized laboratory that initially sends [PIP biological materials] / [clinical specimens] to other laboratories within the [WHO Network] and to other recipients.

“Originating Member State” means the Member State where the [PIP biological materials] / [clinical specimens] were first collected.

“Pandemic Influenza Preparedness Framework” means this Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits. *(Consensus)*

“Influenza Virus Traceability Mechanism” means an IT based system for tracking the transfer and movement of PIP biological materials into, within and out of the [WHO Network] as defined in the framework. *(Consensus)*

“WHO antivirals stockpile” means a reserved quantity of antiviral medicines and associated equipment for management of outbreaks of H5N1 and other influenza viruses with human pandemic potential, as specified in section 6.8 of this framework. *(Consensus)*

“WHO Member States” means the States party to the WHO Constitution. *(Consensus)*

“WHO pandemic influenza preparedness vaccine stockpile” or “PIP vaccine stockpile” is the stockpile of vaccines for H5N1 or other influenza viruses with human pandemic potential referred to in paragraph 6.9 of this Framework. *(Consensus)*

“WHO Secretariat” has the meaning assigned to it in the WHO Constitution. *(Consensus)*

5. PANDEMIC INFLUENZA PREPAREDNESS SYSTEM FOR SHARING OF H5N1 AND OTHER INFLUENZA VIRUSES WITH HUMAN PANDEMIC POTENTIAL

5.1 General

5.1.1 Member States, through their National Influenza Centres and Other authorized laboratories, should in a rapid, systematic and timely manner provide PIP biological materials from all cases of H5N1 and other influenza viruses with human pandemic potential, as feasible [to the WHO Network]: *(Consensus)*

(i) to the WHO Collaborating Centre on Influenza or WHO H5 Reference Laboratory of the originating Member State’s choice, and *(Consensus)*

[(ii) through those laboratories to other WHO Collaborating Centres on Influenza, WHO H5 Reference Laboratories, Essential Regulatory Laboratories, National Influenza Centres and Other authorized laboratories, influenza vaccine, diagnostic and pharmaceutical manufacturers and public health researchers, for the purposes of: [research and development, including for] full virus characterization, pandemic risk assessment, the development and validation of diagnostics and pharmaceuticals, the development of pandemic influenza preparedness vaccine viruses and the development and production of vaccines.]

OR

[(ii) WHO Collaborating Centres on Influenza or WHO H5 Reference Laboratories receiving the PIP biological materials may transfer PIP biological materials only to:

(a) Essential Regulatory Laboratories, [and] NIC [of originating country], solely for the purpose of fulfilling their respective terms of reference;

- (b) Influenza vaccine, diagnostic and pharmaceutical manufacturers solely for the development and/or production of vaccines, diagnostics, pharmaceuticals and Other biological products;
- (c) Other researchers solely for influenza related research other than developing and/or producing vaccines, diagnostics and pharmaceutical products and Other biological products.]
- (iii) Essential Regulatory Laboratories, on receiving PIP biological materials from WHO Collaborating Centres on Influenza or WHO H5 Reference Laboratories may transfer PIP biological materials only to respective WHO Collaborating Centres on Influenza and NICs of the originating country.
- (iv) Influenza vaccine, diagnostic and pharmaceutical manufacturers and other researchers that receive PIP biological materials from WHO Collaborating Centres on Influenza or Essential Regulatory Laboratories will not further transfer those materials to any other person or entity, including institutions, organizations or entities.
- (v) The transfer of PIP biological materials mentioned in 5.1.1(i) and 5.1.1(ii) and 5.1.1(iii) will be done using the standard material transfer agreement in Annex 1¹ and only on due completion and execution of the SMTA of relevant entities.]

5.1.2 By providing PIP biological materials from National Influenza Centres and Other authorized laboratories to WHO Collaborating Centres on Influenza and WHO H5 Reference Laboratories as set out in paragraph 5.1.1(i) above, Member States provide their [prior informed consent] / [consent] for the onward transfer and use of PIP biological materials to the institutions, organizations and entities [as set out in 5.1.1(ii)].

5.1.3 National Influenza Centres and Other authorized laboratories will make, as feasible, efforts to ensure that PIP biological materials, from cases of H5N1 and other influenza viruses with human pandemic potential, that they provide to WHO Collaborating Centres on Influenza and WHO H5 Reference Laboratories: (*Consensus*)

- (i) contain viable material; (*Consensus*) and
- (ii) are accompanied by information as agreed in the traceability mechanism and other clinical and epidemiological information needed for risk assessment. (*Consensus*)

5.1.4 Member States may also provide PIP biological materials directly to any other party or body on a bilateral basis provided that the same materials are provided on a priority basis to the WHO Collaborating Centres on Influenza and/or H5 Reference Laboratories under this Framework. (*Consensus*)

¹ For clarity in document EB128/4, this is termed Attachment 1.

5.2 Genetic sequence data

5.2.1 Genetic sequence data, and analyses arising from that data, relating to H5N1 and other influenza viruses with human pandemic potential should be shared in a rapid, timely and systematic manner with the originating laboratory and among [WHO Network] laboratories. (*Consensus*)

5.2.2 Recognizing that greater transparency and access concerning influenza virus genetic sequence data is important to public health and there is a movement towards the use of public-domain or public-access databases such as Genbank and GISAID respectively; and (*Consensus*)

5.2.3 Recognizing that in some instances the publication of genetic sequence data has been considered sensitive by the country providing the virus: (*Consensus*)

5.2.4 Member States request the Director-General to consult the Advisory Group on the best process for further discussion and resolution of issues relating to the handling of genetic sequence data from H5N1 and other influenza viruses with pandemic potential as part of the Pandemic Influenza Preparedness Framework. (*Consensus*)

5.3 Traceability and reporting mechanisms

5.3.1 The Director-General, in consultation with the Advisory¹ Group, will put in place in a timely manner a transparent traceability mechanism that uses an electronic system in order to track in real time the movement of PIP biological materials into, within, and out of the WHO Network. (*Consensus*)

5.3.2 To ensure that rapid, systematic and timely feedback is provided to Originating laboratories and Member States, the Director-General will also include in the traceability mechanism and associated electronic reporting systems a request that WHO Collaborating Centres, H5 Reference Laboratories and Essential Regulatory Laboratories provide a summary report of laboratory analyses and on request any other available information required by the originating laboratory regarding PIP biological materials. (*Consensus*)

5.3.3 Pending the further development and functioning of subsequent versions of the transparent traceability mechanism, the WHO Secretariat will operate and maintain the current interim system, providing full disclosure of information on the transfer and movement of PIP biological materials into, within and out of the [WHO Network]. (*Consensus*)

5.3.3bis In order to ensure the IVTM does not hinder the functioning of the [WHO Network] during pandemic influenza emergencies, as determined by the Director-General, the Director-General may temporarily modify the requirement to record all PIP biological materials. **The Director-General shall consult the Advisory Group in this regard, including, if appropriate, through electronic means.** Such a modification must be limited to the pandemic virus strain or strains connected with the emergency.

¹ At the November 2007 session of the IGM, the term “advisory mechanism” was substituted for the term “oversight mechanism” used in resolution WHA60.28.

The Director-General shall report on any such modification to the Member States **and shall include in her report the views of the Advisory Group.** (*Consensus*)

5.4 Standard Material Transfer Agreement¹

General

5.4.1 Member States and the Director-General should [require/urge] that [WHO Network] laboratories use the Standard Material Transfer Agreement consistent with Annex 1² to this Framework to cover all transfers [and use] of PIP biological materials as a [mandatory condition].

5.4.2 The Standard Material Transfer Agreement [, [preferably in] [including] electronic form,] will be standardized, universal and globally applicable to all transfers [in, to, within, and out of the [WHO Network] [and use] / [and uses] of PIP biological materials [their uses] and not be subject to further negotiation [, additional permissions].

Execution of the Standard Materials Transfer Agreement

[5.4.4A [The Standard Materials Transfer Agreement will be self-executed in relation to transfers of PIP biological materials [in, to, within, and out of the [WHO Network]] the [WHO Network]] [from National Influenza Centres and authorized laboratories to WHO Collaborating Centres on Influenza and WHO H5 Reference Laboratories and in relation to transfers of PIP biological materials within the WHO Network.]]

[[WHO Network] laboratories transferring PIP biological materials to influenza vaccine, diagnostic and pharmaceutical manufacturers or public health researchers will ensure that those institutions, organizations and entities agree in writing to comply with the Standard Material Transfer Agreement.]]

OR

[[5.4.4B The SMTA will be executed, preferably in electronic form, [including fax] and will be duly completed and signed by the institutions, organizations, and entities providing and receiving PIP biological materials.] or (DELETE 5.3.4B)

6. PANDEMIC INFLUENZA PREPAREDNESS BENEFIT SHARING SYSTEM

6.1 General

6.1.1. Member States should, working with the WHO Secretariat, contribute to a pandemic influenza benefit-sharing system and call upon relevant institutions, organizations, and entities, influenza

¹ Standard Material Transfer Agreement is being used in place of the term “standard terms and conditions” used in resolution WHA60.28.

² For clarity in document EB128/4, this is termed Attachment 1.

vaccines, diagnostics and pharmaceutical manufacturers and public health researchers to also make appropriate contribution to this system. (*Consensus*)

6.1.2 The PIP Benefit Sharing System will operate to:

- (i) provide pandemic surveillance and risk assessment and early warning information and services to all countries; (*Consensus*)
- (ii) provide benefits, including, where appropriate, capacity building in pandemic surveillance, risk assessment, and early warning information and services to Member States. (*Consensus*)
- (iii) prioritize important benefits, such as and including antiviral medicines and vaccines against H5N1 and other influenza viruses with human pandemic potential as high priorities, to developing countries, particularly affected countries, according to public health risk and needs and particularly where those countries do not have their own capacity to produce or access influenza vaccines, diagnostics and pharmaceuticals. Prioritization will be based on assessment of public health risk and need, by experts with transparent guidelines; (*Consensus*)
- (iv) build capacity in receiving countries over time for and through technical assistance and transfer of technology, skills and know-how and expanded influenza vaccine production, tailored to their public health risk and needs. (*Consensus*)

6.1.3 The Pandemic Influenza Preparedness Benefit Sharing System will include the elements set out in the remainder of this part. (*Consensus*)

6.2 Pandemic risk assessment and risk response

6.2.1 [WHO Network] laboratories will make available to the WHO Secretariat and the originating Member State, in a rapid, systematic and timely manner, a summary report of laboratory analyses and on request any other available information required regarding PIP biological materials to enable the affected countries and in particular, developing countries, an effective and meaningful risk response. (*Consensus*)

6.2.2 WHO will provide information on risk response including, but not limited to, information on development of vaccines, candidate virus and effective antivirals to all affected countries and in particular, to developing countries, to enable an effective and meaningful risk response. (*Consensus*)

6.2.3 The WHO Secretariat will make available to all Member States, in a rapid, systematic and timely way, pandemic risk assessments and assist with risk response with all necessary supporting information. (*Consensus*)

6.2.4 WHO Collaborating Centres on Influenza and WHO H5 Reference Laboratories and the Director-General will actively continue to provide technical assistance to Member States to enhance research and surveillance capacity, including staff training, with the objective of improving national pandemic risk assessment and pandemic risk response. (*Consensus*)

6.3 Provision of PIP Candidate Vaccine Viruses

6.3. The Director-General will ensure that WHO Collaborating Centres on Influenza/H5 Reference Labs and Essential Regulatory Laboratories, as agreed in the Terms of Reference, provide PIP candidate vaccine viruses upon request (*Consensus*)

- (i) to influenza vaccine manufacturers on a no preference basis (*Consensus*)
- (ii) at the same time to the laboratories of originating and other Member States (*Consensus*)
- (iii) to any other laboratory (*Consensus*)

6.3bis Any entity receiving PIP candidate vaccine viruses will meet appropriate biosafety guidelines (*WHO Laboratory Biosafety Manual*, 3rd edition) and employ laboratory protection best practices. (*Consensus*)

6.4 Provision of diagnostic reagents and test kits

6.4.1 WHO Collaborating Centres on Influenza, WHO H5 Reference Laboratories and Essential Regulatory Laboratories, working with the WHO Secretariat, will continue to make available to National Influenza Centres and Other authorized laboratories, without charge, supplies of noncommercial diagnostic reagents and test kits for the identification and characterization of clinical specimens of influenza. (*Consensus*)

6.4.2 Influenza diagnostic manufacturers receiving PIP biological materials are urged to make available to [WHO Network] laboratories, without charge or at concessional and/or preferential rates, supplies of diagnostic reagents and test kits for the identification and characterization of clinical specimens of influenza, if circumstances warrant. (*Consensus*)

6.5 Provision of reference reagents for potency determination of vaccines

6.5.1 Essential regulatory laboratories (ERLs) will continue to provide, upon request, reference reagents for potency determination of vaccines against H5N1 and other viruses of human pandemic potential to national regulatory laboratories and influenza vaccine manufacturers of all Member States. (*Consensus*)

6.5.2 ERLs will continue to provide upon request, training in quality control of vaccines against H5N1 and other viruses of human pandemic potential to national regulatory laboratories of all Member States. (*Consensus*)

6.6 Laboratory and influenza surveillance capacity building

6.6.1 Upon request, Member States with advanced laboratory and influenza surveillance capacity are urged to continue to work with WHO and other Member States, particularly developing countries to develop national laboratory and influenza surveillance capacity, including: (*Consensus*)

- (i) to conduct early detection, isolation and characterization of viruses; (*Consensus*)
- (ii) to participate in pandemic risk assessment and response; (*Consensus*)

- (iii) to develop research capacity related to influenza; (*Consensus*)
- (iv) to achieve technical qualifications for consideration of laboratories as National Influenza Centres, WHO H5 Reference Laboratories and WHO Collaborating Centres on Influenza. (*Consensus*)

6.7 Regulatory capacity building

6.7.1 Upon request, Member States with advanced regulatory capacity should improve and strengthen the work that has been undertaken by Member States with WHO, particularly developing countries to strengthen the capacity of regulatory authorities to carry out the necessary measures for the rapid approval of safe and effective human influenza vaccines, diagnostics and pharmaceutical products, including products developed from the use of PIP biological materials, especially those derived from new sub-types of influenza viruses. (*Consensus*)

6.7.2 Member States should make publicly available information on the notification of health regulatory approval of vaccines, diagnostics and pharmaceutical products for H5N1 and other influenza viruses with human pandemic potential, including those developed from the use of PIP biological materials. (*Consensus*)

6.8 Antivirals stockpiles (*Consensus*)

6.8.1 The Director-General will continue to work with other multilateral agencies, donors, international philanthropic organizations/entities, private foundations, and other potential partners, including institutions, organizations and entities and in particular influenza vaccine, diagnostic and pharmaceutical manufacturers, to seek commitments for contributions, maintain and further develop a stockpile of antiviral medicines and associated equipment for use in containment of outbreaks of H5N1 and other influenza viruses with human pandemic potential. (*Consensus*)

6.8.2 The Director-General will continue to coordinate with Member States, institutions, organizations and other entities and encourage them to maintain and further develop stockpiles of antiviral medicines and associated equipment for use in containment of outbreaks of H5N1 and other influenza viruses with human pandemic potential. (*Consensus*)

6.8.3 The Director-General will continue to seek the guidance of expert advice in determining the size, composition, replenishment, operational use and deployment procedures for use of the WHO antivirals stockpile. (*Consensus*)

6.9 Pandemic influenza preparedness vaccine stockpile

6.9.1 The Director-General will establish and maintain a stockpile of vaccines for H5N1 and other influenza viruses with human pandemic potential and associated equipment, including syringes, needles and applicators, consistent with expert guidance. (*Consensus*)

6.9.2 The WHO stockpile will initially include 150 million doses of H5N1 vaccine for use in accordance with expert guidance including SAGE. Indicatively: (*Consensus*)

- (i) 50 million doses will be for use in affected countries, according to public health risk and need, to assist in containing the first outbreak or outbreaks of an emerging pandemic; and (*Consensus*)

- (ii) 100 million doses will be for distribution, once a pandemic begins, to developing countries that have no or inadequate access to H5N1 influenza vaccines, on a per capita basis, with use to be determined by those countries. (*Consensus*)

6.9.3 Member States should urge influenza vaccine manufacturers to prioritize and respond to the needs of the WHO PIP vaccine stockpile and to donate sufficient doses of vaccines for H5N1 to meet its initial target (see 6.9.1 above). (*Consensus*)

6.9.4 The Director-General will continue to seek the guidance of experts in determining the size, composition, replenishment and operational use of the vaccines in the WHO PIP vaccine stockpile for H5N1 and other influenza viruses with human pandemic potential. (*Consensus*)

6.9.5 If insufficient doses are donated, the Director-General will work with Member States to explore the use of sustainable financing mechanisms (see 6.14 below) to meet the requirements of the WHO PIP vaccine stockpile. (*Consensus*)

6.9.5bis The Director-General will, with the guidance of experts, keep under review the potential for the pre-pandemic use of the WHO PIP vaccine stockpile in affected countries, including by supporting trials as appropriate. (*Consensus*)

6.9.6 The Director-General will work with relevant experts and Member States to develop and exercise operational plans for the deployment of the vaccines in the WHO PIP vaccine stockpile. (*Consensus*)

6.10 Access to vaccines in the inter-pandemic period for developing countries

6.10.1 Separately from measures to support the WHO PIP vaccine stockpile set out at article 6.9 above:

6.10.1.1 Member States should urge influenza vaccine manufacturers to set aside a portion of each production cycle of vaccines for H5N1 and other influenza viruses with human pandemic potential for stockpiling and/or use, as appropriate, by developing countries; and (*Consensus*)

6.10.1.2 Member States should continue to work with each other, with the Director-General and with influenza vaccine manufacturers, with the aim of ensuring that adequate quantities of vaccines for H5N1 and other influenza viruses with human pandemic potential are made available to developing countries at the same time as to developed countries, on the basis of public health risk and needs and at tiered prices (see 6.12 below). (*Consensus*)

6.11 Access to pandemic influenza vaccines

6.11.1 Member States should urge vaccine manufacturers to set aside a portion of each production cycle of pandemic influenza vaccine for use by developing countries; and (*Consensus*)

6.11.2 The Director-General, consulting Member States and the Advisory Group, will convene an expert group to continue to develop international mechanisms, including existing ones, for the production and distribution of influenza vaccines on the basis of public health risk and needs during a pandemic, for consideration by the World Health Assembly in 2010. (*Consensus*)

6.12 Tiered pricing

6.12.1 As a measure to improve the affordability for developing countries of pandemic influenza vaccines and vaccines for H5N1 and other influenza viruses with human pandemic potential, and antivirals, Member States should urge influenza vaccine and antiviral manufacturers individually to implement tiered pricing for these vaccines and antivirals. As part of this approach, influenza vaccine and antiviral manufacturers individually should be urged to consider the income level of the country, and negotiate with the national authorities, of the recipient country in arriving at the price to be applied in the private and public markets of each country. In this context the vulnerability of the least developed countries should be taken into account. (*Consensus*)

6.13 Technology transfer

6.13.1 The Director-General will continue to work closely with Member States and influenza vaccine manufacturers to implement the WHO Global Pandemic Influenza Action Plan to Increase Vaccine Supply, including its strategies to build new production facilities in developing and/or industrialized countries and through transfer of technology, skills and know-how. (*Consensus*)

6.13.2 Member States should urge influenza vaccine, diagnostic and pharmaceutical manufacturers to make specific efforts to transfer these technologies to other countries, particularly developing countries, as appropriate. (*Consensus*)

6.13.3 Technology transfer should be conducted in a manner consistent with applicable national laws and international laws and obligations, facilitated progressively over time, on mutually agreed terms, and be suitable to the capacity of recipient Member States, to empower developing countries to study and manufacture influenza vaccines, diagnostics and pharmaceuticals. (*Consensus*)

6.13.4 Influenza vaccine manufacturers who receive PIP biological materials may grant, subject to any existing licensing restrictions, on mutually agreed terms, a non-exclusive, royalty-free licence to any influenza vaccine manufacturer from a developing country, to use its intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of influenza vaccine development and production, in particular for pre-pandemic and pandemic vaccines for use in agreed developing countries. (*Consensus*)

6.13.5 Member States seeking to receive technology to produce influenza vaccine should be encouraged to first conduct studies on the disease burden of seasonal influenza with related economic analysis in their country. Should the study warrant, Member States should be encouraged to consider incorporating seasonal influenza vaccination into their national immunization programme, which will enable sustainable functioning of the manufacturing facilities. (*Consensus*)

6.14 Sustainable and innovative financing mechanisms

6.14.1 With a view to ensuring the sustainable financing of the PIP benefit sharing system, particularly for developing countries; and (*Consensus*)

6.14.2 Having regard to the desirability of all Member States and recipients of PIP biological materials contributing to the PIP benefit sharing system, financially or in kind, according to their capacity and over time; (*Consensus*)

6.14.3 The Director-General will continue to consult with relevant United Nations agencies, other partner institutions and organizations, influenza vaccine, diagnostic and pharmaceutical manufacturers, relevant experts and Member States to: (*Consensus*)

- (i) review the existing mechanisms for the sustainable financing of pandemic influenza preparedness and response measures (*Consensus*)
- (ii) consider whether and what new sustainable/innovative mechanisms, are required for sustainable financing of the PIP benefit sharing system; and (*Consensus*)
- (iii) report to the World Health Assembly in 2010 on the outcomes of the review as outlined in paragraphs (i) and (ii) above. (*Consensus*)

7. GOVERNANCE AND REVIEW

7.1 General

7.1.1 The implementation of this Framework will be overseen by the World Health Assembly with advice from the Director-General. (*Consensus*)

7.1.2 An oversight mechanism is hereby established, which includes the World Health Assembly, the Director-General and the independent “Advisory Group”, established in connection with the Interim Statement of November 2007, and composed of international experts serving the Organization exclusively. Respectively, their function will be as follows: (*Consensus*)

- (a) The Health Assembly, consistent with the Organization’s Constitutional function to act as the “directing and co-ordinating” authority on international health work, as set forth in Article 2(a) of the WHO Constitution, will oversee implementation of the Framework. (*Consensus*)
- (b) The Director-General, consistent with her role and responsibilities, particularly in connection with Collaborating Institutions and Other Mechanisms of Collaboration, inter alia, will promote implementation of the Framework within WHO and among relevant WHO-related entities. (*Consensus*)
- (c) In order that the Health Assembly and Director-General have appropriate expert monitoring and evaluation processes to support these functions, the Advisory Group, as provided for in this section, will provide evidence-based reporting, assessment and recommendations regarding the functioning of the Framework. The Advisory Group, consistent with WHO practice regarding such independent expert bodies, will advise the Director-General but will not itself engage in administrative functions, such as the recognition, or withdrawal of recognition, of technical institutions, nor will it have a public role, except as authorized. (*Consensus*)

7.2 Advisory Group

7.2.1 The Director-General will maintain the Advisory Group, referenced in section 7.1.2 above, to monitor and provide guidance to strengthen the functioning of the [WHO Network] and undertake necessary assessment of the trust-based system needed to protect public health and to help ensure implementation of this Framework. (*Consensus*)

7.2.2 The Director-General, in consultation with Member States, will continue to ensure that the Advisory Group is based on equitable representation of the WHO regions and of affected countries, taking into account balanced representation between developed and developing countries. (*Consensus*)

7.2.3 The Advisory Group will comprise 18 members drawn from three Member States in each WHO Region, with a skill mix of internationally recognized policy makers, public health experts and technical experts in the field of influenza. (*Consensus*)

7.2.4 The Advisory Group will function to assist the Director-General in monitoring the implementation of this Framework, in accordance with the terms of reference for the Advisory Group at Attachment 2 to this Framework. (*Consensus*)

7.2.5 The Advisory Group will present an annual report to the Director-General on its evaluation of the implementation of this Framework. The report should cover the following:

- (i) necessary technical capacities of [WHO Network]
- (ii) operational functioning of [WHO Network]
- (iii) global [WHO Network] influenza pandemic preparedness priorities, guidelines and best practices (e.g. vaccine stockpiles, capacity building)
- (iv) increasing and enhancing surveillance for H5N1 and other influenza viruses with human pandemic potential
- (v) the Influenza Virus Tracking Mechanism. (*Consensus*)

7.2.6 The Director-General will present a report on the work carried out by the Advisory Group through the Executive Board to the Sixty-third World Health Assembly in 2010 for its consideration including a decision on the Advisory Group's future mandate. (*Consensus*)

7.3 Governance and review of Terms of Reference for [WHO Network] Laboratories

7.3.1 The Terms of Reference of the WHO Collaborating Centres on Influenza, WHO H5 Reference Laboratories, National Influenza Centres and Essential Regulatory Laboratories should be developed in accordance with the guiding principles outlined in Attachment 3 to this Framework.

7.3.2 The Director-General in consultation with the Advisory Group and competent authorities in Member States, and the WHO Collaborating Centres, WHO H5 Reference Laboratories, National Influenza Centres, and Essential Regulatory Laboratories will review periodically the Terms of Reference of the institutions and laboratories of the [WHO Network] and amend them when needed, to promote the principles provided by this Framework, and report thereon to the World Health Assembly. (*Consensus*)

[7.3.3 Member States may bring to the attention of the Director-General allegations of non-compliance by institutions and laboratories of the [WHO Network] with their respective terms of reference [or the Standard Material Transfer Agreement.]]

7.3.4 In the event of any alleged breaches of the Terms of Reference or the [Standard Material Transfer Agreement] by a WHO Collaborating Centre on Influenza, WHO H5 Reference Laboratories or National Influenza Centre, and Essential Regulatory Laboratories, the Director-General will review the circumstances and may discuss with the Advisory Group any appropriate action in response to those breaches. Where there has been a serious breach, the Director-General may consider suspending or revoking the WHO designation of the relevant laboratory. (*Consensus*)

7.5 Review of Framework

7.5.1 The Director-General, in consultation with Member States and the Advisory Group, will report every two years beginning in 2010 on the operation of this Framework and all of its components, including the report of the Advisory Group for consideration by the World Health Assembly, through the Executive Board. The Director-General will submit through the Executive Board a full evaluation on this Framework and all of its components for consideration by the Sixty-seventh World Health Assembly in 2014. (*Consensus*)

ATTACHMENT 1**ANNEX 1****PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK FOR THE SHARING OF INFLUENZA VIRUSES AND ACCESS TO VACCINES AND OTHER BENEFITS****DRAFT TECHNICAL PROVISIONS OF THE STANDARD MATERIAL TRANSFER AGREEMENT****BACKGROUND****General considerations**

The threat of pandemic influenza persists. Timely sharing of surveillance information and highly pathogenic avian influenza viruses, as well as ensuring equitable access to effective vaccinations, medicines and related technology are important aspects of global readiness to respond to the pandemic. The Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (the “Framework”) is an international mechanism to implement a fairer, more transparent, equitable and efficient system. In developing countries, support to implement national integrated human and animal influenza action plans and build national minimum core capacity for detection, risk assessment, laboratory confirmation and rapid containment are critical success factors. (*IGM Text Principles – Introductory paragraph*)¹

Drafting considerations

The following draft standard material transfer agreement has been prepared in response to the request by the Intergovernmental Meeting to the Director-General to prepare “a revised version of the technical part of the Standard Material Transfer Agreement, following the agreed principles of the Intergovernmental Meeting text”.²

The specific part of the request to revise “the technical part” of the Agreement raised a question of interpretation. Many, if not all, of the provisions of the Agreement are technical in some sense, that is to say they are either scientifically or legally technical. Accordingly, and in the interest of completeness, the Secretariat has provided as comprehensive a draft Agreement as possible. The text follows as closely as possible the agreed principles of the Intergovernmental Meeting’s text. Where agreed principles were absent or unclear, placeholder language has been inserted indicating that relevant provisions of the Framework would be added as they become agreed in the course of the intergovernmental process, or an option for consideration has been provided, in all cases clearly indicated as such. Such options are not intended to suggest agreed outcomes but rather to facilitate discussion on the relevant topic.

¹ See document EB124/4 Add.1, Annex 2.

² See document EB124/4 Add.1, Annex 1.

In preparing this draft, the Secretariat examined several models of format and technical provisions, including, in particular, the standard material transfer agreement connected with the International Treaty on Plant Genetic Resources for Food and Agriculture adopted by the Food and Agriculture Organization of the United Nations in 2001 (“the FAO treaty”). Eight other material transfer agreements regularly used or proposed for transfer of biological materials were also reviewed as useful examples of format and technical provisions generally familiar to the community of providers and recipients of biological materials.

Regarding compliance with the standard material transfer agreement, Articles 7 and 8 address applicable law and dispute settlement. They are modelled on the relevant provisions of the agreement in the FAO treaty. As in the case of the latter’s standard material transfer agreement a range of dispute settlement options are provided, including negotiation, mediation and, ultimately, binding arbitration. By its terms, the applicable law, under Article 7, would be the general principles of international commercial law, as opposed to particular domestic law. Enforcement of any arbitral decisions would be in accordance with the aforementioned principles.

Draft Standard Material Transfer Agreement

Preamble

Whereas WHO coordinates a network of influenza laboratories (hereinafter, the “WHO Network”) that conduct pandemic influenza risk assessment and risk response activities under agreed terms of reference;

Whereas enabling the global public health community to prevent, protect against, control and provide a public health response to the threat of pandemic influenza through the Framework is a global public good for health;

Whereas the Framework recognizes that Member States have a commitment to share on an equal footing H5N1 and other influenza viruses of human pandemic potential and the benefits, considering these as equally important parts of the collective action for global public health; (*IGM Text preambular paragraph 3, Consensus*)

Whereas the Parties to the Framework recognize that the commitment to share on an equal footing H5N1 and other influenza viruses of human pandemic potential and the benefits enables WHO Member States and the Director-General to assess the global risk of an influenza pandemic and allows WHO Member States and the Director-General to take actions to reduce the risk of the emergence of a pandemic and to facilitate the development and production of vaccines, diagnostic materials and other pharmaceuticals that can assist in rapidly responding to and containing an emerging pandemic; (*IGM Text preambular paragraph 15, Consensus*)

Whereas the Framework is to be implemented in a manner consistent with relevant national and international laws, regulations, ethical norms, and obligations;

Whereas the objective of the Framework is to improve pandemic influenza preparedness and strengthen the protection against the spread of pandemic influenza by implementing a fair[er, and more] transparent, equitable, efficient and effective system for:

- [(i) the sharing of H5N1 and other influenza viruses with human pandemic potential; and
- (ii) the sharing of the benefits arising from the use of H5N1 and other influenza viruses with human pandemic potential including the generation of information, diagnostics, medicines, vaccines and other technologies.]; (*IGM Text preambular paragraph 2.1*)

Whereas Parties to the Framework have adopted this Standard Material Transfer Agreement, referred to in Section 5.3 of the Framework, for use by all entities that use, transfer or receive influenza viruses through or from the [WHO Network];

OR

[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.]

ARTICLE 1 – PARTIES TO THE AGREEMENT

1.2 This Agreement is:

BETWEEN: *(name and address of the provider or providing institution,¹ name of authorized official, contact information for authorized official)* (hereinafter referred to as “the Provider”), *(Consensus)*

AND: *(name and address of the recipient or recipient institution, name of authorized official, contact information for authorized official)* (hereinafter referred to as “the Recipient”²). *(Consensus)*

1.3 The parties to this Agreement hereby agree as follows:

ARTICLE 2 – DEFINITIONS

[In this Agreement, the definitions and use of terms referred to in Section 4 of the Framework [operative at the date of acceptance] are incorporated herein by reference.]

Add

[Definition of [WHO Network].]

ARTICLE 3 – SUBJECT MATTER OF THE STANDARD MATERIAL TRANSFER AGREEMENT

The materials specified in Appendix 1 are hereby transferred from the Provider to the Recipient subject to the terms and conditions set out in this Agreement. *(Consensus)*

ARTICLE 4 – GENERAL PROVISIONS

4.1 [This Agreement is entered into under the Framework and shall be implemented and interpreted in accordance with the objectives and provisions of said Framework.]

Or

[This Agreement shall be interpreted in accordance with the provisions of the Framework] *(pending preamble)*

¹ This identifies the entity that sends the PIP Biological Materials – it could be, for example, a National Influenza Centre, or a WHO Collaborating Centre or any other institution that transfers PIP Biological Materials to another entity.

² This is the recipient of the PIP Biological Materials in this transaction.

[ARTICLE 5 – RIGHTS AND OBLIGATIONS OF THE PROVIDER]

The Provider undertakes that the Materials specified in Appendix 1 are transferred in accordance with the following provisions:

5.1 The Provider will make the transfer of such Materials in accordance with its applicable WHO Terms of Reference and record the transfer in the WHO Influenza Virus Traceability Mechanism.

Or

5.1 The Provider shall make best efforts to ensure that the materials are handled in accordance with applicable WHO guidelines.

5.2 The Provider shall make best efforts to ensure such Materials are treated as optimally as possible to retain the viability of the materials. (*Consensus*)

Add

[5.3 The Provider should be assured of the results of these studies for which materials are provided in a timely manner.]

[ARTICLE 6 – RIGHTS AND OBLIGATIONS OF THE RECIPIENT]

The Recipient undertakes that the Materials specified in Appendix 1 shall be used or conserved in accordance with the following provisions:

6.1 The Recipient shall record receipt of such Material in the WHO Influenza Virus Traceability Mechanism.

6.1bis [In the event of further transfers, [and either party to this further transfer is [within or outside]/[a member of] [WHO Network] an SMTA will be executed with respect to each such further transfer.]

6.2 Any Recipient that receives Materials in its capacity as a [WHO Network] entity shall handle Materials in accordance with its WHO Terms of Reference. (*Consensus*)

[6.2bis The recipient shall use and further pass on the materials to any other user provided under this agreement only for the purpose specified in Annex 1¹.]

6.3 *The Recipient shall not seek to obtain any intellectual property rights in connection with such Materials, unless the Recipient agrees to grant to WHO a royalty-free, non-exclusive, transferable licence with respect to such rights. WHO may then transfer this licence to developing countries, with appropriate terms and conditions, as determined by the Director-General in accordance with sound public health principles, with transparent rules and procedures, informed by expert guidance and evidence. (Option for consideration)*

¹ For clarity in document EB128/4, this is termed Attachment 1.

6.4 *For a recipient who produces or is capable of producing influenza vaccines: In the event of an influenza pandemic, such a recipient agrees to reserve at least [10]% of doses of pandemic influenza vaccine it produces, after the start of pandemic vaccine production, for purchase, at cost, by organizations in the United Nations system for use first in developing countries. (Option for consideration)*

[Insert other provisions as agreed, such as those concerning publication information and acknowledgement ...]

Or

ARTICLE 4/[5] – RIGHTS AND OBLIGATIONS

[The Provider and the Recipient undertake the following with respect to the materials specified in Appendix 1:

4.1 The Provider shall make best efforts to ensure that the materials are handled in accordance with applicable WHO guidelines. Any Recipient that receives the materials in its capacity as a [WHO Network] entity shall handle the materials in accordance with its WHO Terms of Reference.

4.2 The Provider consents to the onward transfer and use of the materials specified in Appendix 1, including to members of the [WHO Network], other public health researchers, other authorized laboratories, or influenza vaccines, diagnostics and pharmaceutical manufacturers.

4.3 The Provider and the Recipient acknowledge that any intellectual property rights associated with the materials specified in Appendix 1, or their use, will not be affected by this SMTA.]

ARTICLE 7 – APPLICABLE LAW

The applicable law shall be the Principles of International Commercial Contracts 2004 of the International Institute for the Unification of Private Law (UNIDROIT), as well as the objectives, principles and other relevant provisions of the Framework.

Or

[This Agreement shall be governed by the Principles of International Commercial Contracts 2004 of the International Institute for the Unification of Private Law (UNIDROIT).]

ARTICLE 8 – DISPUTE SETTLEMENT

8.1 Dispute settlement may be initiated by the Provider or the Recipient.

8.4 Any dispute arising from this Agreement shall be resolved in the following manner:

(a) amicable dispute settlement: the Parties shall attempt in good faith to resolve the dispute by negotiation;

(b) mediation: If the dispute is not resolved by negotiation, the parties may choose mediation through a neutral third party mediator, to be mutually agreed;

(c) arbitration: If the dispute has not been settled by negotiation or mediation, any Party may submit the dispute for arbitration under the Arbitration Rules of an international body as agreed by the parties to the dispute. Failing such agreement, the dispute shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce, by one or more arbitrators appointed in accordance with the said Rules. 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, or the arbitrators appointed by them, may agree to appoint a sole arbitrator, or presiding arbitrator as the case may be, from such list of experts. The result of such arbitration shall be binding.

8.5 Any costs associated with dispute settlement shall be shared equally between the Parties.

[Or delete]

ARTICLE 9 – ADDITIONAL ITEMS

Warranty

9.1 Notwithstanding provision 5.2, the Provider makes no warranties as to the safety of the PIP Biological Materials, nor as to the accuracy or correctness of any data provided with them. Neither does it 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.

Duration of Agreement

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

[Or delete]

ARTICLE [6/10 – SIGNATURE/ACCEPTANCE

This SMTA shall be a “click-wrap” agreement if executed by electronic means, or a “shrink-wrap” agreement otherwise, unless either party requires this Agreement to be executed by signature of a printed document. All three methods are equally valid, binding and enforceable to confirm acceptance of this Agreement and only one method is required to establish acceptance. (*Consensus*)

Method 1 – Acceptance by signature of printed document

I, (*Full Name of Authorized Official*), represent and warrant that I have the authority to execute this Agreement on behalf of the **Provider** and acknowledge my institution’s responsibility and obligation to abide by the provisions of this Agreement. [, both by letter and in principle, in order to promote the sustainable sharing of PIP Biological Materials and benefits under the Framework.]

Signature.....

Date

Name of the Provider.....

I, (*Full Name of Authorized Official*), represent and warrant that I have the authority to execute this Agreement on behalf of the **Recipient** and acknowledge my institution's responsibility and obligation to abide by the provisions of this Agreement. [, both by letter and in principle, in order to promote sustainable sharing of PIP biological materials and benefits under the Framework.]

Signature

Date.....

Name of the Recipient.....

Or

Method 1 – Acceptance by signature of printed document

I, (*Full Name of Authorized Official*), represent and warrant that I have the authority to execute this Agreement on behalf of the **Provider** and acknowledge my institution's responsibility and obligation to abide by the provisions of this Agreement.

Signature

Date.....

Name of the Provider

I, (*Full Name of Authorized Official*), represent and warrant that I have the authority to execute this Agreement on behalf of the **Recipient** and acknowledge my institution's responsibility and obligation to abide by the provisions of this Agreement.

Signature

Date.....

Name of the Recipient.....

Method 2 – Acceptance of Agreement by acceptance of PIP Biological Materials (Shrink-wrap Standard Material Transfer Agreements)¹

The [PIP Biological] Materials are provided conditional on acceptance of the terms of this Agreement. The provision of the [PIP Biological] Materials[specified in Appendix 1²] by the Provider and the Recipient's acceptance of the [PIP Biological] Materials [(i.e., the retention of the materials expressed by the signature of the courier's delivery documentation)] constitutes acceptance of the terms of this Agreement.

Or

¹ A "shrink-wrap" Standard Material Transfer Agreement is where a copy of the Standard Material Transfer Agreement is included in the packaging of the PIP Biological Materials, and the Recipient's acceptance of the PIP Biological Materials constitutes acceptance of the terms and conditions of the Standard Material Transfer Agreement.

² For clarity in document EB128/4, this is termed subattachment 1.

Method 2 – Acceptance of Agreement by acceptance of Materials (Shrink-wrap Standard Material Transfer Agreements)¹

The materials are provided conditional on acceptance of the terms of this Agreement. The provision of the materials specified in Appendix 1² by the Provider and the Recipient's acceptance of the materials constitutes acceptance of the terms of this Agreement.

Method 3 – Acceptance of Agreement electronically (Click-wrap Standard Material Transfer Agreement)³

The [PIP Biological] Materials are provided upon acceptance of this Agreement concluded through electronic means[, such as the Internet. For example, “digital signature” may be used instead of physical signatures to establish acceptance of the terms of this Agreement.]

Or

Method 3 – Acceptance of Agreement electronically (Click-wrap Standard Material Transfer Agreement)²

The materials are provided upon acceptance of this Agreement concluded through electronic means.

¹ A “shrink-wrap” Standard Material Transfer Agreement is where a copy of the Standard Material Transfer Agreement is included in the packaging of the materials, and the Recipient's acceptance of the materials constitutes acceptance of the terms and conditions of the Standard Material Transfer Agreement.

² For clarity in document EB128/4, this is termed subattachment 1.

³ A “click-wrap” Standard Material Transfer Agreement is where the agreement is concluded on the Internet and the Recipient accepts the terms and conditions of the Standard Material Transfer Agreement by clicking on the appropriate icon on the web site or in the electronic version of the Standard Material Transfer Agreement, as appropriate.

SUBATTACHMENT 1

APPENDIX

LIST OF MATERIALS PROVIDED

This Appendix¹ contains a list of the PIP Biological Materials provided under this Agreement:
[List to be completed by Provider]

¹ For clarity in document EB128/4, this is termed subattachment 1.

ATTACHMENT 2

**ADVISORY GROUP
TERMS OF REFERENCE**

(Adopted by the Intergovernmental Meeting at its resumed session in December 2008)

1. Background and mandate of Advisory Group

The Interim Statement adopted by WHO Member States attending the session of the Intergovernmental Meeting on Pandemic Influenza Preparedness on 20–23 November 2007 urged action to develop fair, transparent, and equitable international mechanisms on virus sharing and benefit sharing. Member States called on the Director-General to establish an Advisory Mechanism to monitor, provide guidance to strengthen the functioning of the trust-based system needed to protect public health and undertake necessary assessment of that system. To carry this out, Member States specified that an Advisory Group will be appointed by the Director-General in consultation with Member States, based on equitable representation of the WHO regions and of affected countries.

The trust-based system is now referred to as the “Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits” (hereinafter “the Framework”). The scope of the Advisory Group is to monitor, assess and report on the system for sharing H5N1 influenza viruses and other influenza viruses with human pandemic potential as well as access to vaccines and other benefits of the Framework. The institutional components of the Framework to be monitored by the Advisory Group are National Influenza Centres, Other authorized laboratories, WHO Collaborating Centres, H5 Reference Laboratories, and Essential Regulatory Laboratories, as defined in Section [4] of the Framework. The pharmaceutical industry, although not included, can be consulted by the Advisory Group.

2. Functions of the Advisory Group

2.1 To monitor, assess and report on how the different functions of the Framework are implemented by its components. The information to conduct these tasks should be provided by the WHO Secretariat and other independent sources, if available. Monitoring by the Advisory Group will enable ongoing assessment of the functioning of the Framework and should include at least:

- (a) the rapid, systematic and timely sharing of H5N1 and other influenza viruses with human pandemic potential with the [WHO Network];
- (b) the Influenza Virus Traceability Mechanism;
- (c) the global improvement of laboratory capacity, particularly in developing countries, to enhance pandemic influenza preparedness;
- (d) the fair and equitable sharing of benefits.

2.2 To carry out the necessary assessment of the Framework according to quantitative and qualitative indicators developed from information provided by the WHO Secretariat and other independent sources, if necessary.

- 2.3 To provide guidance to strengthen the functioning of the Framework to the Director-General.
- 2.4 Recommendations and reports of the Advisory Group shall be evidence based.
- 2.5 To report annually, through the Director-General to the Executive Board and the World Health Assembly on its activities.

3. Nomination of members

3.1 The Advisory Group will comprise 18 members drawn from three Member States in each WHO region, with a skill mix of internationally recognized policy makers, public health experts and technical experts in the field of influenza. In the exercise of their functions the Members shall act as international experts serving WHO exclusively.

3.2 Each member will serve for three years. The duration of appointment of each member will be three years with a renewal of one third of the members every year; replacements must maintain the equitable representation of the six WHO regions and affected countries; all members will be eligible for two appointments. In the event of resignation or incapacity of a member for any reason, the Director-General will appoint a replacement member with a view to maintaining the equitable representation of the six WHO regions and affected countries. The replacement will complete the term of the previous member. The Group will select from among its members, a Chairperson and a Vice-Chairperson. The Chairperson and Vice-Chairperson will serve for two years after which another Chairperson and Vice-Chairperson will be selected by the Group members.

3.3 The Director-General will regularly accept nominations of representatives and will draw from this list to replace outgoing members with a view to maintaining the equitable representation of the six WHO regions and affected countries.

4. Working procedures

4.1 The Director-General will apply to this Advisory Group working procedures consistent with WHO's practices and procedures.

4.2 The Regulations for Expert Advisory Panels and Committees will apply to the Advisory Group, including with respect to the private nature of meetings. Furthermore, members of the Advisory Group will not make public statements, individually or on behalf of the Group, on the work of the Advisory Group, except as authorized in connection with reporting requirements or by the Director-General.

5. Resources for implementation

The Director-General will make available the necessary human and financial resources to support the work of the Advisory Group.

ATTACHMENT 3

WHO COLLABORATING CENTRES FOR INFLUENZA**TERMS OF REFERENCE RELATED TO WORK WITH PANDEMIC
INFLUENZA PREPAREDNESS BIOLOGICAL MATERIALS****BACKGROUND**

The [WHO Network] serves as a global alert mechanism for the emergence of influenza viruses with important features, including those with pandemic potential. For activities related to pandemic influenza, the [WHO Network] includes four complementary categories of institutions and laboratories: National Influenza Centres, WHO Collaborating Centres, WHO H5 Reference Laboratories and Essential Regulatory Laboratories. The [WHO Network] is coordinated by the WHO Global Influenza Programme. Within each category all institutions and laboratories perform functions defined by core Terms of Reference. The core Terms of Reference for WHO Collaborating Centres are the minimum requirements that must be met by each WHO Collaborating Centre and the capacity to fulfil these is a prerequisite to designation as a WHO Collaborating Centre. Each laboratory or institution that is formally recognized or designated as a part of the Network by WHO has accepted to be bound by the core Terms of Reference applicable to its category. The following are the core Terms of Reference applicable to the WHO Collaborating Centres.

In addition, individual WHO Collaborating Centres within the Network may have additional Specific Terms of Reference, where appropriate. The Specific Terms of Reference recognize that there are differences in expertise, capacities and interests among the WHO Collaborating Centres and provide for individual WHO Collaborating Centres to perform additional functions related to pandemic risk assessment and response. Specific Terms of Reference will be discussed with and agreed upon between the WHO Collaborating Centre and the WHO Global Influenza Programme before the WHO Collaborating Centre's designation and redesignation.

In general, the WHO Collaborating Centres conduct influenza pandemic risk assessment on an ongoing basis and provide advice, expertise and support to Member States and the Secretariat to facilitate activities in response to influenza risks. The WHO Collaborating Centres support outbreak investigation, conduct comprehensive virus analyses, and select and develop candidate influenza vaccine viruses with pandemic potential. The efficient implementation pandemic influenza risk assessment and risk response is based on the collective efforts of all [WHO Network] members and through the rapid sharing of biological materials, reference reagents, epidemiologic data and other information.

It is understood that the Guiding Principles, as agreed by the Intergovernmental Meeting and reproduced below, will guide all activities, specific Terms of Reference or associated functions of the [WHO Network] laboratories when they act in their capacity as a [WHO Network] laboratory. The Terms of Reference for all [WHO Network] laboratories have been developed under the following overarching Guiding Principles:

Guiding Principles for the development of Terms of Reference for current and potential future [WHO Network] laboratories for H5N1 and other human pandemic influenza viruses

1. *All activities conducted by [WHO Network] laboratories under their WHO Terms of Reference will be consistent with the [Framework and the] Standard Material Transfer Agreement.*
2. *The [WHO Network] laboratories will be coordinated by, and provide support to, WHO.*
3. *The [WHO Network] laboratories will provide a timely summary report of laboratory analyses and on request any other available information on tests conducted, test results and associated risk assessment and risk response as is specified in their Terms of Reference.*
4. *The [WHO Network] laboratories will share experience and provide capacity strengthening support to WHO Member States within their resources where necessary.*
5. *The [WHO Network] laboratories will provide support as specified in their Terms of Reference for the development of potential pandemic vaccine, pandemic vaccine, diagnostic test materials and pharmaceuticals.*
6. *If [WHO Network] laboratories conduct research on influenza viruses received for public health surveillance purposes, they will do so in a manner that includes participation of scientists, to the fullest extent possible, from the submitting National Influenza Centre or other authorized laboratory, especially those from developing countries, including through the publication process.*
7. *The [WHO Network] laboratories will support global public health preparedness and response, especially for urgent situations including international outbreaks and epidemics.*
8. *The [WHO Network] laboratories will share in a rapid, systematic and timely manner biological materials related to pandemic influenza preparedness, using the Influenza Virus Traceability Mechanism as appropriate, including distribution to other qualified laboratories, to facilitate public health risk assessment, risk response activities and scientific research in accordance with the Standard Material Transfer Agreement.*
- [9. *The [WHO Network] laboratories will submit genetic sequences data to GISAID and Genbank or similar databases in a timely manner consistent with the Standard Material Transfer Agreement.]]*[[Consensus]]
- [10. *The PIP biological materials received by the [WHO Network] laboratories will be provided [due credit] and recognition to the submitting National Influenza Centre or other authorized laboratory.*]

Core Terms of Reference

WHO Collaborating Centres for Influenza are centres of excellence on influenza which are designated by WHO and which agree to the following:

A. General conditions and activities

1. Work under the coordination of the WHO Global Influenza Programme, and provide support to WHO (Guiding Principles 2, 7);

2. fulfil the Core Terms of Reference and Specific Terms of Reference using financial support provided only by governmental and/or other non-commercial sources;
3. use the WHO Influenza Virus Traceability Mechanism to record the receipt and transfer of PIP biological materials (Guiding Principle 8);
4. comply with the [Standard Material Transfer Agreement] of the Pandemic Influenza Preparedness Framework for Sharing of Influenza viruses and access to vaccines and other benefits. (Guiding Principle 1);
5. maintain the capacity to exchange materials and information on a regular and timely basis with other WHO Collaborating Centres (Guiding Principles 3, 8);
6. have full and unrestricted access to biosafety level 3 laboratory facilities that meet recognized international and national standards. The Provider assumes full responsibility for complying with their respective national biosecurity and biosafety regulations on the understanding that such regulations and rules shall, at a minimum, meet the relevant and current WHO standards;
7. serve as a technical resource to WHO for any other urgent issues related to pandemic influenza or influenza outbreaks with pandemic potential (Guiding Principles 2, 5);
8. appropriately acknowledge the originating laboratories providing clinical specimens and/or influenza viruses with pandemic potential (Guiding Principles 8, 10);
9. maintain and strengthen active communication and collaboration with National Influenza Centres¹ and WHO to ensure that up-to-date information and findings of public health significance are rapidly exchanged (Guiding Principles 3, 4, 7, 8);
10. alert WHO and the country from which clinical specimens and/or viruses with pandemic potential were provided, on unusual findings related to pandemic influenza risk assessment (Guiding Principles 3, 7);
11. provide expertise and laboratory support when requested by WHO, to assist Member States, and in particular developing countries, in responding to outbreaks of influenza viruses with pandemic potential and risk assessment (Guiding Principles 2, 3, 4, 7);
12. provide training and laboratory support to National Influenza Centres, especially those in developing countries, on laboratory techniques and skills, including diagnosis, data analyses, risk assessment and other critical capacities (Guiding Principle 4);
13. assist WHO in improving global surveillance for influenza viruses with pandemic potential (Guiding Principles 2, 7) including the development of standards, recommendations and policies as well as improving associated outbreak response and pandemic preparedness (Guiding Principles 2, 3, 4, 7);

¹ WHO designated National Influenza Centres <http://www.who.int/csr/disease/influenza/centres/en/index.html>.

14. provide regular and timely surveillance data and results of virus characterization to originating laboratories and to WHO (Guiding Principle 3, 7);
15. advise the [WHO Network] on laboratory methods for diagnosis of influenza viruses with pandemic potential, including the adoption of new diagnostic approaches, the improvement of laboratory practices and other operational needs (Guiding Principles 2, 3, 5).

B. Laboratory analyses and related activities

1. Conduct accurate laboratory diagnosis, typing and subtyping, and confirmation of influenza A(H5) and other influenza viruses with pandemic potential for specimens received (Guiding Principles 2, 3, 7);
2. conduct isolation of influenza viruses with pandemic potential in embryonated eggs and cell culture;
3. conduct detailed antigenic and genetic analyses of influenza viruses with pandemic potential and make the results available to WHO and the originating laboratories in a timely manner (Guiding Principles 2, 3, 4, 7);
4. share available haemagglutinin, neuraminidase and other gene sequences of A(H5) and other influenza viruses with pandemic potential immediately with the originating laboratory, WHO Collaborating Centres and H5 Reference Laboratories (Guiding Principle 3);
5. upload available haemagglutinin, neuraminidase and other gene sequences of A(H5) and other influenza viruses with pandemic potential to a publicly accessible database in a timely manner but no later than three months after sequencing is completed, unless otherwise instructed by the laboratory or country providing the clinical specimens and/or viruses (Guiding Principle 9);
6. produce and distribute ferret antisera against influenza viruses with pandemic potential to WHO laboratories involved in influenza vaccine virus selection and development (Guiding Principle 5);
7. conduct analyses, provide data and advice to WHO and participate in meetings and teleconferences concerning the selection, development and timely availability of candidate vaccine viruses for H5N1 and other influenza viruses with pandemic potential (Guiding Principles 2, 5, 7);
8. participate in the development of candidate influenza vaccine viruses for pandemic influenza preparedness and response (Guiding Principles 5, 7);
9. conduct antiviral susceptibility testing of H5N1 and other influenza viruses with pandemic potential and provide timely reports to the originating laboratories and WHO (Guiding Principle 3);
10. select, maintain and update a group of reference influenza viruses with pandemic potential, including H5N1, and corresponding antisera if available and update the availability of candidate influenza vaccine viruses and corresponding antisera, if any, to WHO (Guiding Principles 2, 3, 5, 7);
11. develop, update and produce laboratory diagnostic reagents for influenza H5N1 and other viruses with pandemic potential directly or through contracted entities, and distribute them to National Influenza Centres subject to the availability of resources (Guiding Principle 5);

12. share in a timely manner clinical specimens and influenza viruses with pandemic potential in accordance with [the Standard Material Transfer Agreement] with laboratories working in coordination and collaboration with the WHO Global Influenza Programme, including:

- (i) other WHO Collaborating Centres (Guiding Principles 1, 8);
- (ii) essential regulatory laboratories that are involved in the WHO process of candidate influenza vaccine virus selection and development, as well as vaccine potency reagent development (Guiding Principles 1, 8);
- (iii) other laboratories involved in WHO coordinated specialized activities (e.g. the WHO External Quality Assessment Project for the detection of subtype influenza A viruses using polymerase chain reaction; the WHO influenza polymerase chain reaction primer updating), and other activities whose purpose is to strengthen global influenza surveillance and other risk assessment and risk response; as well as capacity building (Guiding Principles 1, 4, 8);

13. select candidate influenza vaccine viruses under the coordination of WHO, for development and production of vaccines against influenza viruses with pandemic potential. Depending on the vaccine production process, the candidate influenza vaccine viruses can include wild type viruses and high-growth reassortant viruses, including those prepared by reverse genetics. Distribute candidate influenza vaccine viruses to appropriate recipients with appropriate biosafety level capacity on request, including influenza vaccine manufacturers, diagnostic companies, research institutes and others interested in receiving influenza vaccine viruses (Guiding Principles 5, 8);

14. select, maintain and update reference A(H5N1) and other influenza viruses with pandemic potential as antigenically and genetically representative of important groups of viruses. Subject to the availability of resources, distribute both reference viruses and corresponding antisera, on request, to National Influenza Centres and other institutes for non-commercial activities including surveillance, and reference and research (Guiding Principle 10);

15. [seek approval from the laboratories providing the original clinical specimens and/or viruses for distribution of influenza clinical specimens and/or influenza viruses with pandemic potential for purposes beyond those described above.]

C. Research and scientific presentations and publications

1. Actively seek the participation of scientists from originating laboratories/countries in scientific projects associated with research on clinical specimens and/or influenza viruses from their countries and actively engage them in preparation of manuscripts for presentation and publication (Guiding Principle 6);

2. appropriately acknowledge in presentations and publications, the contributions of collaborators, including laboratories/countries providing clinical specimens or influenza viruses with pandemic potential or reagents, using guidelines such as those outlined by the International Committee of Medical Journal Editors¹ (Guiding Principle 6).

¹ See <http://www.icmje.org/>.

Specific Terms of Reference

These are additional functions attributed to an individual WHO Collaborating Centre in light of its specific expertise in the field of influenza. (*Consensus*)

NATIONAL INFLUENZA CENTRES

TERMS OF REFERENCE RELATED TO WORK WITH PANDEMIC INFLUENZA PREPAREDNESS BIOLOGICAL MATERIALS

BACKGROUND

The [WHO Network] serves as a global alert mechanism for the emergence of influenza viruses with important features, including those with pandemic potential. For activities related to pandemic influenza, the [WHO Network] includes four complementary categories of institutions and laboratories: National Influenza Centres, WHO Collaborating Centres, WHO H5 Reference Laboratories and Essential Regulatory Laboratories. The [WHO Network] is coordinated by the WHO Global Influenza Programme. Within each category all institutions and laboratories perform functions defined by core Terms of Reference. Each laboratory or institution that is formally recognized or designated as a part of the Network by WHO has accepted to be bound by the core Terms of Reference applicable to its category. The following are the core Terms of Reference applicable to the National Influenza Centres.

National Influenza Centres play a key role in pandemic influenza risk assessment by alerting WHO immediately to outbreaks of H5N1 or other influenza viruses with pandemic potential. National Influenza Centres collect specimens from suspected cases of H5N1 or other unusual influenza viral infection, perform laboratory diagnosis and analysis, and ship in a timely manner, such specimens or viruses isolated from them, to a WHO Collaborating Centre or H5 Reference Laboratory for advanced virological analysis. Efficient pandemic influenza risk assessment and risk response are based on collective efforts from all [WHO Network] members through rapid exchange of biological materials, reference reagents, epidemiologic data and other information.

It is understood that the Guiding Principles, as agreed by the Intergovernmental Meeting and reproduced below, will guide all activities, specific Terms of Reference or associated functions of the [WHO Network] laboratories when they act in their capacity as a [WHO Network] laboratory. The Terms of Reference for all [WHO Network] laboratories have been developed under the following overarching Guiding Principles:

Guiding Principles for the development of Terms of Reference for current and potential future [WHO Network] laboratories for H5N1 and other human pandemic influenza viruses

- 1. All activities conducted by [WHO Network] laboratories under their WHO Terms of Reference will be consistent with the [Framework and the] Standard Material Transfer Agreement*
- 2. The [WHO Network] laboratories will be coordinated by, and provide support to, WHO.*
- 3. The [WHO Network] laboratories will provide a timely summary report of laboratory analyses and on request any other available information on tests conducted, test results and associated risk assessment and risk response as is specified in their Terms of Reference.*
- 4. The [WHO Network] laboratories will share experience and provide capacity strengthening support to WHO Member States within their resources where necessary.*

5. *The [WHO Network] laboratories will provide support as specified in their Terms of Reference for the development of potential pandemic vaccine, pandemic vaccine, diagnostic test materials and pharmaceuticals.*

6. *If [WHO Network] laboratories conduct research on influenza viruses received for public health surveillance purposes, they will do so in a manner that includes participation of scientists, to the fullest extent possible, from the submitting National Influenza Centre or other authorized laboratory, especially those from developing countries, including through the publication process.*

7. *The [WHO Network] laboratories will support global public health preparedness and response, especially for urgent situations including international outbreaks and epidemics.*

8. *The [WHO Network] laboratories will share in a rapid, systematic and timely manner PIP biological materials, using the Influenza Virus Traceability Mechanism as appropriate, including distribution to other qualified laboratories, to facilitate public health risk assessment, risk response activities and scientific research in accordance with the Standard Material Transfer Agreement.*

[9. *The [WHO Network] laboratories will submit genetic sequences data to GISAID and Genbank or similar databases in a timely manner consistent with the Standard Material Transfer Agreement.*][[Consensus]]

[10. *The PIP biological materials received by the [WHO Network] laboratories will be provided [due credit] and recognition to the submitting National Influenza Centre or other authorized laboratory.*]

Core Terms of Reference

National Influenza Centres are laboratories that fulfil the Terms of Reference listed below. A National Influenza Centre is formally designated by the health ministry of the country concerned and is recognized by WHO. A National Influenza Centre may have additional obligations under the authority of its Ministry of Health.

A. General conditions and activities

1. Work under the coordination of the WHO Global Influenza Programme and provide support to WHO (Guiding Principles 2, 7);

2. use the WHO Influenza Virus Traceability Mechanism to record the receipt and transfer of PIP biological materials (Guiding Principle 8);

3. comply with the [Standard Material Transfer Agreement of the Pandemic Influenza Preparedness Framework for Sharing of Influenza viruses and access to vaccines and other benefits] (Guiding Principle 1);

4. serve as a key point of contact between WHO and the country of the National Influenza Centre on issues related to surveillance, laboratory diagnosis, and sharing of clinical specimens and/or influenza viruses with pandemic potential, as well as sharing of important related clinical or epidemiological information, when available, with WHO (Guiding Principles 2, 3, 4, 7, 8);

5. participate actively in WHO pandemic influenza surveillance activities and maintain active communication and collaboration with other members of the [WHO Network] (Guiding Principles 4, 7, 8).

B. Laboratory and related activities

1. Collect or process as appropriate clinical specimens from patients suspected to be infected with H5N1 and other influenza viruses with pandemic potential (Guiding Principle 7);
2. act as a collection point for virus isolates of suspected pandemic influenza from laboratories within the country;
3. conduct testing of clinical specimens for influenza viruses and detect influenza viruses that cannot be readily identified with diagnostic reagents provided through the [WHO Network];
4. ship, within one week, clinical specimens and/or viruses [and/ or RNA or cDNA] that cannot be readily identified with diagnostic reagents provided through the [WHO Network] to a WHO Collaborating Centre or H5 Reference Laboratory of their choice of] and include the date the specimen was collected and relevant geographical, epidemiological and clinical information (Guiding Principles 2, 3, 5, 7, 8); (*Consensus*)
5. attend laboratory training courses provided by the WHO Collaborating Centres in an effort to establish and maintain capacity to recognize influenza viruses that cannot be readily identified (Guiding Principle 4);
6. review, maintain and strengthen influenza surveillance in the country (Guiding Principle 2);
7. provide technical advice and support to other influenza laboratories in the country on specimen collection and shipment logistics, laboratory biosafety and other operational procedures related to influenza surveillance (Guiding Principles 2, 7).

C. Information and communication

1. Alert WHO immediately when influenza viruses are detected that cannot be readily identified with diagnostic reagents provided through the [WHO Network] or when unusual outbreaks of non-seasonal influenza or influenza-like illness emerge;
2. provide national authorities and the general public with information on H5N1 and other influenza viruses with pandemic potential circulating in the country in a timely manner.

WHO H5 REFERENCE LABORATORIES

TERMS OF REFERENCE RELATED TO WORK WITH PANDEMIC INFLUENZA PREPAREDNESS BIOLOGICAL MATERIALS

BACKGROUND

The [WHO Network] serves as a global alert mechanism for the emergence of influenza viruses with important features, including those with pandemic potential. For activities related to pandemic influenza, the [WHO Network] includes four complementary categories of institutions and laboratories: National Influenza Centres, WHO Collaborating Centres, WHO H5 Reference Laboratories and Essential Regulatory Laboratories. The [WHO Network] is coordinated by the WHO Global Influenza Programme. Within each category all institutions and laboratories perform functions defined by core Terms of Reference. The core Terms of Reference for WHO Collaborating Centres are the minimum requirements that must be met by each WHO Collaborating Centre and the capacity to fulfil these is a prerequisite to designation as a WHO Collaborating Centre. Each laboratory or institution that is formally recognized or designated as a part of the Network by WHO has accepted to be bound by the core Terms of Reference applicable to its category. The following are the core Terms of Reference applicable to the H5 Reference Laboratories.

WHO H5 Reference Laboratories are laboratories that were designated by WHO on an *ad hoc basis* commencing in 2005, to support the [WHO network] in response to the emergence and spread of highly pathogenic avian influenza H5N1. These laboratories conduct influenza risk assessment and response by providing reliable laboratory diagnosis of influenza infection in humans, especially those suspected of being associated with avian influenza A(H5) viruses or other influenza viruses with pandemic potential. Efficient influenza risk assessment and risk response are based on collective efforts from all [WHO Network] members through rapid exchange of biological materials, reference reagents, epidemiologic data and other information.

It is understood that the Guiding Principles, as agreed by the Intergovernmental Meeting and reproduced below, will guide all activities, specific Terms of Reference or associated functions of the [WHO Network] laboratories when they act in their capacity as a [WHO Network] laboratory. The Terms of Reference for all [WHO Network] laboratories have been developed under the following overarching Guiding Principles:

Guiding Principles for the development of Terms of Reference for current and potential future [WHO Network] laboratories for H5N1 and other human pandemic influenza viruses

1. *All activities conducted by [WHO Network] laboratories under their WHO Terms of Reference will be consistent with the [Framework and the] Standard Material Transfer Agreement.*
2. *The [WHO Network] laboratories will be coordinated by, and provide support to, WHO.*
3. *The [WHO Network] laboratories will provide a timely summary report of laboratory analyses and on request any other available information on tests conducted, test results and associated risk assessment and risk response as is specified in their Terms of Reference.*

4. *The [WHO Network] laboratories will share experience and provide capacity strengthening support to WHO Member States within their resources where necessary.*
5. *The [WHO Network] laboratories will provide support as specified in their Terms of Reference for the development of potential pandemic vaccine, pandemic vaccine, diagnostic test materials and pharmaceuticals.*
6. *If [WHO Network] laboratories conduct research on influenza viruses received for public health surveillance purposes, they will do so in a manner that includes participation of scientists, to the fullest extent possible, from the submitting National Influenza Centre or other authorized laboratory, especially those from developing countries, including through the publication process.*
7. *The [WHO Network] laboratories will support global public health preparedness and response, especially for urgent situations including international outbreaks and epidemics.*
8. *The [WHO Network] laboratories will share in a rapid, systematic and timely manner PIP biological materials, using the Influenza Virus Traceability Mechanism as appropriate, including distribution to other qualified laboratories, to facilitate public health risk assessment, risk response activities and scientific research in accordance with the Standard Material Transfer Agreement.*
9. *The [WHO Network] laboratories will submit genetic sequences data to GISAID and Genbank or similar databases in a timely manner consistent with the Standard Material Transfer Agreement.]]*[[Consensus]]
10. *The PIP biological materials received by the [WHO Network] laboratories will be provided [due credit] and recognition to the submitting National Influenza Centre or other authorized laboratory.]*

Core Terms of Reference

WHO H5 Reference Laboratories are laboratories which are designated through a defined WHO process, on an *ad hoc* basis, and which meet the core Terms of Reference listed below.

A. General conditions and activities

1. Work under the coordination of the WHO Global Influenza Programme; and provide support to WHO (Guiding Principle 2);
2. meet the WHO criteria for accepting positive results of H5 infection in humans;¹
3. use the WHO Influenza Virus Traceability Mechanism to record the receipt and transfer of PIP biological materials (Guiding Principle 8);
4. comply with the [Standard Material Transfer Agreement of the PIP Framework for Sharing of Influenza viruses and access to vaccines and other benefits.] (Guiding Principle 1);

¹ See http://www.who.int/csr/disease/avian_influenza/H5AcceptanceCriteria_16Oct07.pdf.

5. provide laboratory services to its own country and other countries when needed for diagnosis of influenza A(H5) and other influenza viruses with pandemic potential (Guiding Principles 3, 7);
6. alert WHO and the country that provided clinical specimens and/or viruses with pandemic potential about unusual findings related to pandemic influenza risk assessment (Guiding Principles 3, 7);
7. provide feedback to WHO on the use of WHO recommended diagnostic protocols and primers to assist WHO in updating laboratory diagnostic recommendations (Guiding Principles 2, 3, 4, 5).

B. Laboratory and other activities

1. Provide advice to clinics, hospitals and other specimen collection sites on safe and appropriate clinical specimen collection, storage, packaging and shipping (Guiding Principle 7);
2. conduct accurate laboratory diagnosis, typing and subtyping and confirmation of influenza A(H5) and other influenza viruses with pandemic potential for specimens received and make the results available to WHO Collaborating Centres and the originating laboratories in a timely manner (Guiding Principles 2, 3, 4, 7);
3. provide expertise and laboratory support in response to outbreaks of A(H5) and other influenza viruses with pandemic potential (Guiding Principles 2, 3, 4, 5, 7);
4. routinely share clinical specimens and/or virus isolates from A(H5) and other influenza viruses with pandemic potential with WHO Collaborating Centres for further characterization in accordance with [the Standard Material Transfer Agreement] (Guiding Principles 1, 8, 10);
5. share available haemagglutinin, neuraminidase and other gene sequences of A(H5) and other influenza viruses with pandemic potential immediately with the originating laboratory, WHO Collaborating Centres and H5 Reference Laboratories (Guiding Principle 3);
6. upload available haemagglutinin, neuraminidase and other gene sequences of A(H5) and other influenza viruses with pandemic potential to a publicly accessible database in a timely manner, but no later than three months after sequencing is completed, unless otherwise instructed by the laboratory or country providing the clinical specimens and/or viruses (Guiding Principle 9);
7. appropriately acknowledge the originating laboratories providing clinical specimens and/or influenza viruses with pandemic potential (Guiding Principles 8, 10).

C. Research, scientific presentations and publications

1. Actively seek the participation of scientists from originating laboratories/countries in scientific projects associated with research on clinical specimens and/or influenza viruses from their countries and actively engage them in preparation of manuscripts for presentation and publication (Guiding Principle 6);
2. appropriately acknowledge in presentations and publications, the contributions of collaborators, including laboratories/countries providing clinical specimens or influenza viruses with pandemic

potential or reagents, using guidelines such as those outlined by the International Committee of Medical Journal Editors¹ (Guiding Principle 6).

¹ See <http://www.icmje.org/>.

ESSENTIAL REGULATORY LABORATORIES

TERMS OF REFERENCE RELATED TO WORK WITH PANDEMIC INFLUENZA PREPAREDNESS BIOLOGICAL MATERIALS

BACKGROUND

The [WHO Network] serves as a global alert mechanism for the emergence of influenza viruses with important features, including those with pandemic potential. For activities related to pandemic influenza, the [WHO Network] includes four complementary categories of institutions and laboratories: National Influenza Centres, WHO Collaborating Centres, WHO H5 Reference Laboratories and Essential Regulatory Laboratories. The [WHO Network] is coordinated by the WHO Global Influenza Programme. Within each category all institutions and laboratories perform functions defined by core Terms of Reference. The core Terms of Reference for WHO Collaborating Centres are the minimum requirements that must be met by each Collaborating Centre and the capacity to fulfil these is a prerequisite to designation as a WHO Collaborating Centre. Each laboratory or institution that is formally recognized or designated as a part of the Network by WHO has accepted to be bound by the core Terms of Reference applicable to its category. The following are the core Terms of Reference applicable to the Essential Regulatory Laboratories.

Essential Regulatory Laboratories are formally associated with national regulatory agencies, and have a critical role in developing, regulating and standardizing influenza vaccines. They have performed this role for nearly four decades within the WHO Network, and have thereby contributed to the production of safe and effective influenza vaccines through the selection and development of candidate vaccine viruses. While they previously had no formal Terms of Reference with WHO, in practice, they worked closely with both WHO and the influenza vaccine manufacturers. Currently there are four Collaborating Centres: the Center for Biologics Evaluation and Research, United States of America; the National Institute for Biological Standards and Control, United Kingdom of Great Britain and Northern Ireland; the National Institute for Infectious Diseases, Japan, and the Therapeutic Goods Administration, Australia.

The core Terms of Reference are the minimum requirements that must be met by each Essential Regulatory Laboratory, either individually or as a group. Specific Terms of Reference may be discussed with and agreed upon by the Essential Regulatory Laboratory, the WHO Global Influenza Programme and, in some cases, industry before recognition.

It is understood that the Guiding Principles, as agreed by the Intergovernmental Meeting and reproduced below, will guide all activities, specific Terms of Reference or associated functions of the [WHO Network] laboratories when they act in their capacity as a [WHO Network] laboratory. The Terms of Reference for all [WHO Network] laboratories have been developed under the following overarching Guiding Principles:

Guiding Principles for the development of Terms of Reference for current and potential future [WHO Network] laboratories for H5N1 and other human pandemic influenza viruses

1. *All activities conducted by [WHO Network] laboratories under their WHO Terms of Reference will be consistent with the [Framework and the] Standard Material Transfer Agreement.*

2. *The [WHO Network] laboratories will be coordinated by, and provide support to, WHO.*
3. *The [WHO Network] laboratories will provide a timely summary report of laboratory analyses and on request any other available information on tests conducted, test results and associated risk assessment and risk response as is specified in their Terms of Reference.*
4. *The [WHO Network] laboratories will share experience and provide capacity strengthening support to WHO Member States within their resources where necessary.*
5. *The [WHO Network] laboratories will provide support as specified in their Terms of Reference for the development of potential pandemic vaccine, pandemic vaccine, diagnostic test materials and pharmaceuticals.*
6. *If [WHO Network] laboratories conduct research on influenza viruses received for public health surveillance purposes, they will do so in a manner that includes participation of scientists, to the fullest extent possible, from the submitting National Influenza Centre or other authorized laboratory, especially those from developing countries, including through the publication process.*
7. *The [WHO Network] laboratories will support global public health preparedness and response, especially for urgent situations including international outbreaks and epidemics.*
8. *The [WHO Network] laboratories will share in a rapid, systematic and timely manner PIP biological materials, using the Influenza Virus Traceability Mechanism as appropriate, including distribution to other qualified laboratories, to facilitate public health risk assessment, risk response activities and scientific research in accordance with the Standard Material Transfer Agreement.*
- [9. *The [WHO Network] laboratories will submit genetic sequences data to GISAID and Genbank or similar databases in a timely manner consistent with the Standard Material Transfer Agreement.]]*[Consensus]
- [10. *The PIP biological materials received by the [WHO Network] laboratories will be provided [due credit] and recognition to the submitting National Influenza Centre or other authorized laboratory.*]

Core Terms of Reference

Essential Regulatory Laboratories meet the following core Terms of Reference listed below, either individually or as a group:

A. General conditions and activities

1. Advise WHO on the selection of H5N1 and other influenza viruses with pandemic potential for use in influenza vaccines (Guiding Principles 2, 3, 5);
2. assist WHO and Member States in developing vaccine-related aspects of preparedness and response plans for pandemic influenza (Guiding Principles 2, 3, 4, 7);
3. advise WHO on relevant regulatory and development aspects of vaccines for H5N1 and other influenza viruses with pandemic potential (Guiding Principles 2, 3, 5);

4. when requested, inform and advise WHO on work programmes and new technologies aimed at improving development and standardization of vaccines for H5N1 and other influenza viruses with pandemic potential (Guiding Principles 2, 3, 4, 5);
5. use the WHO Influenza Virus Traceability Mechanism to record the receipt and transfer of PIP biological materials (Guiding Principles 8);
6. comply with the [Standard Material Transfer Agreement of the Pandemic Influenza Preparedness Framework for sharing of influenza viruses and access to vaccines and other benefits] (Guiding Principle 1).

B. Laboratory and related activities

1. Store, and, if required, amplify representative H5N1 and other influenza viruses with pandemic potential obtained from the [WHO Network] for the purpose of developing influenza vaccine viruses (Guiding Principles 1, 2);
2. on request by WHO, develop candidate H5N1 and other influenza vaccine viruses with pandemic potential and characterize them using agreed standards (Guiding Principles 1, 2, 3, 5, 6);
3. store, and, if required, amplify candidate H5N1 and other influenza vaccine viruses with pandemic potential obtained from the [WHO Network] (Guiding Principles 1, 2, 3, 5);
4. prepare and calibrate reference reagents for standardization of candidate influenza vaccine viruses for H5N1 and other influenza viruses with pandemic potential in conjunction with other Essential Regulatory Laboratories (Guiding Principles 1, 2, 5);
5. distribute, subject to the Standard Material Transfer Agreement, candidate influenza vaccine viruses for H5N1 and other influenza viruses with pandemic potential to interested laboratories, including laboratories within the [WHO Network] and influenza vaccine manufacturers (Guiding Principles 1, 2, 5);
6. directly or through contractors, supply reference reagents for standardization of H5N1 and other potential pandemic influenza vaccines to laboratories, such as laboratories within the [WHO Network], national regulatory laboratories and influenza vaccine manufacturers (Guiding Principles 1, 2, 5);
7. analyse, provide data and advice to WHO and participate in meetings and teleconferences concerning the selection, development and timely availability of candidate vaccine viruses for H5N1 and other influenza viruses with pandemic potential (Guiding Principles 2, 5, 7).

C. Research and scientific presentations and publications

1. Actively seek the participation of scientists from originating laboratories/countries in scientific projects associated with research on clinical specimens and/or influenza viruses from their countries and actively engage them in preparation of manuscripts for presentation and publication (Guiding Principle 6);
2. appropriately acknowledge in presentations and publications, the contributions of collaborators, including laboratories/countries providing clinical specimens or influenza viruses with pandemic

potential or reagents, using guidelines such as those outlined by the International Committee of Medical Journal Editors¹ (Guiding Principle 6).

¹ See <http://www.icmje.org/>.

ATTACHMENT 4

**GUIDING PRINCIPLES FOR THE DEVELOPMENT OF TERMS OF REFERENCE
FOR CURRENT AND POTENTIAL FUTURE [WHO NETWORK] LABORATORIES
FOR H5N1 AND OTHER HUMAN PANDEMIC INFLUENZA VIRUSES**

The specific roles, responsibilities and activities conducted by the different [WHO Network] laboratories can differ depending on whether they are a National Influenza Centre, a WHO Collaborating Centre, an H5 Reference Laboratory or an essential regulatory laboratory. However, in the context of pandemic influenza preparedness and their work with H5N1 and other viruses of human pandemic potential, the development of the Terms of Reference for each group of [WHO Network] laboratories shall comply with the following core guiding principles.

1. All activities conducted by [WHO Network] laboratories under their WHO Terms of Reference will be consistent with the [Framework and the] Standard Material Transfer Agreement.
2. The [WHO Network] laboratories will be coordinated by, and provide support to, WHO.
3. The [WHO Network] laboratories will provide a timely summary report of laboratory analyses and on request any other available information on tests conducted, test results and associated risk assessment and risk response as is specified in their Terms of Reference.
4. The [WHO Network] laboratories will share experience and provide capacity strengthening support to WHO Member States where necessary.
5. The [WHO Network] laboratories will provide support as specified in their Terms of Reference for the development of potential pandemic vaccine, pandemic vaccine, diagnostic test materials and pharmaceuticals.
6. If [WHO Network] laboratories conduct research on influenza viruses received for public health surveillance purposes, they will do so in a manner that includes participation of scientists, to the fullest extent possible, from the submitting National Influenza Centre or Other authorized laboratory, especially those from developing countries, including through the publication process.
7. The [WHO Network] laboratories will support global public health preparedness and response, especially for urgent situations including international outbreaks and epidemics.
8. The [WHO Network] laboratories will share in a rapid, systematic and timely manner PIP biological materials, using the Influenza Virus Traceability Mechanism as appropriate, including distribution to other qualified laboratories, to facilitate public health risk assessment, risk response activities and scientific research in accordance with the Standard Material Transfer Agreement.
- [9. The [WHO Network] laboratories will submit genetic sequences data to the Global Initiative on Sharing Avian Influenza Data (GISAID) and Genbank or similar databases in a timely manner consistent with the Standard Material Transfer Agreement.][[Consensus]]
- [10. The PIP biological materials received by the [WHO Network] laboratories will be provided [due credit] and recognition to the submitting National Influenza Centre or Other authorized laboratory.]

APPENDIX 2

This appendix contains the text of document A63/48, Appendix 2 originally presented to the Sixty-third World Health Assembly, **as amended** by the Open-Ended Working Group of Member States on Pandemic Influenza Preparedness: sharing of influenza viruses and access to vaccines and other benefits at its meeting in Geneva from 13 to 17 December 2010.

White Paper 1

SMTA Proposal from the Co-Chairs

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.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

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.

¹ Other entities may be included as “Parties”.

[ARTICLE 2A – GENERAL PROVISION

2A. 1 This Agreement is entered into within the context of the “Pandemic Influenza Preparedness: sharing of influenza viruses and access to vaccines and other benefits” Framework and shall be implemented and interpreted in accordance with the objectives and provisions of the Framework.

2A.2 The parties to this Agreement agree that the World Health Organization is the third party beneficiary under this Agreement.

2A.3 The rights granted to WHO do not prevent the Provider and the Recipient from exercising their rights under this Agreement.

2A.4 Where a Party to this Agreement is an “Other authorized laboratory”, the Terms of Reference of a National Influenza Centre shall apply to such Party.]

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. (*Consensus*)

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

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.

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.” N.B. As requested, the Secretariat provides the following reference to the current relevant Guidelines: 1) Laboratory biorisk management for laboratories handling pandemic influenza A (H1N1) 2009 virus; 2) Safe transport of pandemic influenza A (H1N1) 2009 virus cultures, isolates and patient specimens as Biological Substance, Category B; 3) Guidance to Influenza Laboratories Diagnosing Swine Influenza A/H1N1 Infections of current concern.

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 SMTA2¹] [that any such transfer shall be accompanied by a copy of the attached “Standards terms and conditions for the transfer of Materials”].**

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

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.² (*Consensus*)

4.1.3 The Recipient shall inform t WHO of shipments of Materials to entities inside/outside the WHO Network by recording in the IVTM (*Consensus*)

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 antivirals, for pandemic influenza preparedness purposes.]

¹ White Paper 3.

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.” N.B. As requested, the Secretariat provides the following reference to the current relevant Guidelines: 1) Laboratory biorisk management for laboratories handling pandemic influenza A (H1N1) 2009 virus; 2) Safe transport of pandemic influenza A (H1N1) 2009 virus cultures, isolates and patient specimens as Biological Substance, Category B; 3) Guidance to Influenza Laboratories Diagnosing Swine Influenza A/H1N1 Infections of current concern.

[3.1.3 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]

[4.3 The recipient shall not seek to obtain any intellectual property rights in connection with such materials or over any products, processes, other inventions developed using the material.]

[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.] / [the originating laboratories.]]

4.4 In the event of further transfers within the WHO network, the recipient shall do so in accordance with this SMTA. (*Consensus*)

[4.5 In the event of further transfers outside the WHO network, the recipient shall do so in accordance with SMTA2.¹] **[that any such transfer shall be accompanied by a copy of the attached "Standards terms and conditions for the transfer of Materials".]**

4.6 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*)

¹ White Paper 3.

[4.7 Appropriately acknowledge in presentation 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 4 A APPLICABLE LAW]

The applicable law shall be the General Principles of Law, including the Principles of International Commercial Contracts 2004 of the International Institute for the Unification of Private Law (UNIDROIT), as well as the objectives, principles and other relevant provisions of the Framework, and when necessary for interpretation, the decisions taken by the World Health Assembly.]

ARTICLE 5 – DISPUTE RESOLUTION/[SETTLEMENT]

[In the event of a dispute under this SMTA, Parties shall first seek an amicable settlement. Should this fail, [the only other method for seeking dispute resolution shall be that] 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.¹]

Or

[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 discuss with the advisory group any appropriate action in response to the dispute. The Director-General may consider suspending or revoking the WHO designation of the relevant laboratory.]

Or

[6.1 Dispute settlement may be initiated by the Provider or the Recipient.

6.2 Any dispute arising from this Agreement shall be resolved in the following manner:

- (a) amicable dispute settlement: the Parties shall attempt in good faith to resolve the dispute by negotiation;
- (b) mediation: If the dispute is not resolved by negotiation, the parties may choose mediation through a neutral third party mediator, to be mutually agreed;
- (c) **arbitration: If the dispute has not been settled by negotiation or mediation, any Party may submit the dispute for arbitration under the Arbitration Rules of an international body as agreed by the parties to the dispute. Failing such agreement, the dispute shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce, by one or more arbitrators appointed in accordance with the said Rules. 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, or the**

¹ As provided in Section 7.3.4 of the Framework.

arbitrators appointed by them, may agree to appoint a sole arbitrator, or presiding arbitrator as the case may be, from such list of experts. The result of such arbitration shall be binding.

6.3 Any costs associated with dispute settlement shall be shared equally between the Parties.]

[6.1 Dispute settlement may be initiated by the Provider or the Recipient.

6.1.1 The parties to this Agreement agree that the World Health Organization [or the Providing Member State(s)] has the right as third party beneficiary to initiate dispute settlement procedures regarding rights and obligations of the Provider and Recipient under this Agreement.

6.1.2 The third party beneficiary also has the right to request all relevant information including samples as necessary be made available by the Provider or Recipient regarding their obligations in the context of this Agreement. Any information or samples so requested shall be provided by the Provider or Recipient as the case may be.

The dispute settlement procedures are as follows:

ARTICLE X WARRANTY & INDEMNITIES OR ADDITIONAL ITEMS

Notwithstanding provision 5.2, the Provider makes no warranties as to the safety of the PIP Biological Materials, nor as to the accuracy or correctness of any data provided with them. Neither does it 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 Y DURATION OF AGREEMENT

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

ARTICLE 6 – ACCEPTANCE AND APPLICABILITY

[Acceptance by laboratories of the WHO Terms of Reference, as contained in the Framework, constitutes their acceptance of this SMTA.] / [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 [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.

Or

[ARTICLE 8 – SIGNATURE/ACCEPTANCE]

This SMTA shall be a “click-wrap” arrangement if executed by electronic means, or a “shrink-wrap” agreement otherwise, unless either party requires this Agreement to be executed by signature of a printed document. All three methods are equally valid, binding and enforceable to confirm acceptance of this Agreement and only one method is required to establish acceptance.]

[ARTICLE 8 – SIGNATURE/ACCEPTANCE]

This SMTA shall be a “click-wrap” arrangement if executed by electronic means, or a “shrink-wrap” agreement otherwise, unless either party requires this Agreement to be executed by signature of a printed document. All three methods are equally valid, binding and enforceable to confirm acceptance of this Agreement and only one method is required to establish acceptance.]

The Provider and the Recipient may choose the method of acceptance unless either party requires this Agreement to be signed.

Option 1 – Acceptance by signature of printed document

I, (Full Name of Authorized Official), represent and warrant that I have the authority to execute this Agreement on behalf of the Provider and acknowledge my institution’s responsibility and obligation to abide by the provisions of this Agreement.

Signature..... Date.....

Name of the Provider.....

*Designation of the Provider (e.g. whether NIC or WHO CC or H5RL or ERL)
.....*

I, (Full Name of Authorized Official), represent and warrant that I have the authority to execute this Agreement on behalf of the Recipient and acknowledge my institution’s responsibility and obligation to abide by the provisions of this Agreement.

Signature..... Date.....

Name of the Recipient.....

*Designation of the Recipient (e.g. whether NIC or WHO CC or H5RL or ERL)
.....*

Option 2 – Shrink-wrap Standard Material Transfer Agreements

The Material is provided conditional on acceptance of the terms of this Agreement.

The provision of the Material specified in Annex --- by the Provider and the Recipient's acceptance and use of the Materials constitutes acceptance of the terms of this Agreement.

Option 3 – Click-wrap Standard Material Transfer Agreement

The Material is provided upon acceptance of this Agreement concluded through electronic means.

☐ *I hereby agree to the above conditions.]*

White Paper 1

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. Recipients of the WHO PIP Materials 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.

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

- 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-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.

White Paper 2

SMTA 1 Proposal from Brazil, India and Indonesia**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.

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. In this Agreement:

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

and

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

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

ARTICLE 2 – SUBJECT MATTER OF THE AGREEMENT

2.1 PIP Biological Materials, genetic sequences, 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 undertakes the following with respect to the Materials:

3.1.1 To comply with their respective WHO Network Terms of Reference and the Framework

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

3.3 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.

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.”

3.4 The Provider consents to the onward transfer of the Materials to entities outside the WHO Network **on the condition that any such transfer shall be accompanied by SMTA – 2.**

3.5. Provider will inform WHO of shipments of Materials to entities inside and outside the WHO Network for recording in the Influenza Virus Traceability Mechanism.

ARTICLE 4 – RIGHTS AND OBLIGATIONS OF THE RECIPIENTS

4. 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.

4.1 The Recipient shall record receipt of such Material in the WHO IVTM.

4.2. In the event of further transfers within the WHO Network, an SMTA will be executed with respect to each such further transfer.

4.3. The Recipient shall not seek to obtain any intellectual property rights in connection with such Materials.

4.4. Actively seek the participation of scientists from originating laboratories/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.

4.Y. Appropriately acknowledge in presentation 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 5 – APPLICABLE LAW

The applicable law shall be the Principles of International Commercial Contracts 2004 of the International Institute for the Unification of Private Law (UNIDROIT), as well as the objectives, principles and other relevant provisions of the Framework.

ARTICLE 6 – DISPUTE SETTLEMENT

6.1 Dispute settlement may be initiated by the Provider or the Recipient.

6.2 Any dispute arising from this Agreement shall be resolved in the following manner:

(a) amicable dispute settlement: the Parties shall attempt in good faith to resolve the dispute by negotiation;

(b) mediation: If the dispute is not resolved by negotiation, the parties may choose mediation through a neutral third party mediator, to be mutually agreed;

(c) arbitration: If the dispute has not been settled by negotiation or mediation, any Party may submit the dispute for arbitration under the Arbitration Rules of an international body as agreed by the parties to the dispute. Failing such agreement, the dispute shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce, by one or more arbitrators appointed in accordance with the said Rules. 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, or the arbitrators appointed by them, may agree to appoint a sole arbitrator, or presiding arbitrator as the case may be, from such list of experts. The result of such arbitration shall be binding.

5.3 Any costs associated with dispute settlement shall be shared equally between the Parties.

ARTICLE 7 – ADDITIONAL ITEMS

Warranty

9.1 Notwithstanding provision 5.2, the Provider makes no warranties as to the safety of the PIP Biological Materials, nor as to the accuracy or correctness of any data provided with them. Neither does it 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.

Duration of Agreement

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

ARTICLE 8 – SIGNATURE/ACCEPTANCE

This SMTA shall be a “click-wrap” arrangement if executed by electronic means, or a “shrink-wrap” agreement otherwise, unless either party requires this Agreement to be executed by signature of a printed document. All three methods are equally valid, binding and enforceable to confirm acceptance of this Agreement and only one method is required to establish acceptance.

White Paper 3

SMTA 2 Proposal from Brazil, India and Indonesia**Draft Standard Material Transfer Agreement 2****PREAMBLE**

.....

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.

THE PARTIES TO THIS AGREEMENT HEREBY AGREE AS FOLLOWS:**ARTICLE 1 – PARTIES TO THE AGREEMENT**

1.1 Parties to this SMTA 2 include influenza laboratories that have been designated or recognized by WHO that have accepted to work under agreed WHO Terms of Reference and entities outside WHO Network. In this Agreement:

- The Provider is a WHO Network laboratory or an entity outside the WHO Network sending Materials, as herein defined,

(name and address of the provider or providing institution, name of authorized official, contact information for authorized official) (hereinafter referred to as “the Provider”),

and

- The Recipient is the entity outside the WHO Network receiving Materials, as herein defined.

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

(name and address of the recipient or recipient institution, name of authorized official, contact information for authorized official) (hereinafter referred to as “the Recipient”).

ARTICLE 2 – SUBJECT MATTER OF THE AGREEMENT

2.1 PIP Biological Materials, genetic sequences, 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 2A – GENERAL PROVISION

2A.1 This Agreement is entered into within the context of the “Pandemic Influenza Preparedness: sharing of influenza viruses and access to vaccines and other benefits” Framework and shall be implemented and interpreted in accordance with the objectives and provisions of the Framework.

2A.2 The parties to this Agreement agree that the World Health Organization is the third party beneficiary under this Agreement.

2A.3 The rights granted to WHO do not prevent the Provider and the Recipient from exercising their rights under this Agreement.

ARTICLE 3 – RIGHTS AND OBLIGATIONS OF THE PROVIDER

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

3.1.1 To comply with their respective WHO Network Terms of Reference and the Framework where applicable

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

3.3 The Provider agrees to the onward transfer and use of the Materials, to any on the same terms and conditions as those provided in this SMTA.

3.4 The Provider consents to the onward transfer of the Materials to entities outside the WHO Network **on the condition that any such transfer shall be accompanied by a copy of the attached “SMTA – 2”.**

3.5. Provider will inform WHO of shipments of Materials to entities inside and outside the WHO Net work for recording in the Influenza Virus Traceability Mechanism.

ARTICLE 4 – RIGHTS AND OBLIGATIONS OF THE RECIPIENTS

4.1 Recipients shall:

- record receipt of such material in the WHO IVTM
- in the event of further transfers, execute SMTA 2 with respect to each such further transfer
- grant to WHO royalty free, non-exclusive, transferable license with respect to such rights. WHO may then transfer this license to developing countries, with appropriate terms and conditions, as determined by the Director-General in accordance with sound public health principles, and transparent rules and procedures, informed by expert guidance and evidence.

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.”

- pay, in accordance with charge structure
- provide donations of 10% of production to WHO stockpile
- provide under tiered pricing vaccines, antivirals, and diagnostics;
- transfer technology, skills, know how and processes to developing countries on an ongoing basis enabling them to conduct research, development and produce vaccines, reagents and antiviral medicines in a timely manner;
- promote capacity-building;
- support the strengthening of the laboratory and influenza surveillance capacity

[The recipient shall not seek or claim intellectual property rights over the material or its genetic and other parts and components in any form]

4.1.3 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 antivirals, for pandemic influenza preparedness purposes.

4.2. Actively seek the participation of scientists from originating laboratories/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.

4.3. Appropriately acknowledge in presentation and publications, the contributions of collaborators, including laboratories/countries providing clinical specimens or influenza virus with pandemic potential or reagents, using existing scientific guidelines.

4.4: The Recipient shall use the Material solely for research and development pertaining to treatment of influenza with human pandemic potential.

4.5 The Recipient shall make available to WHO Member states through the WHO Secretariat, all non-confidential information that results from the research and development carried out on the Material.

ARTICLE 5 – APPLICABLE LAW

The applicable law shall be the Principles of International Commercial Contracts 2004 of the International Institute for the Unification of Private Law (UNIDROIT), as well as the objectives, principles and other relevant provisions of the Framework.

ARTICLE 6 – DISPUTE SETTLEMENT

6.1 Dispute settlement may be initiated by the Provider or the Recipient.

6.1.1 The parties to this Agreement agree that the World Health Organization [or the Providing Member State(s)] has the right as third party beneficiary to initiate dispute settlement procedures regarding rights and obligations of the Provider and Recipient under this Agreement.

6.2 Any dispute arising from this Agreement shall be resolved in the following manner:

- (a) amicable dispute settlement: the Parties shall attempt in good faith to resolve the dispute by negotiation;
- (b) mediation: If the dispute is not resolved by negotiation, the parties may choose mediation through a neutral third party mediator, to be mutually agreed;
- (c) arbitration: If the dispute has not been settled by negotiation or mediation, any Party may submit the dispute for arbitration under the Arbitration Rules of an international body as agreed by the parties to the dispute. Failing such agreement, the dispute shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce, by one or more arbitrators appointed in accordance with the said Rules. 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, or the arbitrators appointed by them, may agree to appoint a sole arbitrator, or presiding arbitrator as the case may be, from such list of experts. The result of such arbitration shall be binding.

6.1.2 The third party beneficiary also has the right to request all relevant information including samples as necessary be made available by the Provider or Recipient regarding their obligations in the context of this Agreement. Any information or samples so requested shall be provided by the Provider or Recipient as the case may be.

6.3 Any costs associated with dispute settlement shall be shared equally between the Parties.

ARTICLE 7 – ADDITIONAL ITEMS

Warranty

7.1 Notwithstanding provision 5.2, the Provider makes no warranties as to the safety of the PIP Biological Materials, nor as to the accuracy or correctness of any data provided with them. Neither does it 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.

Duration of Agreement

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

ARTICLE 7 – SIGNATURE/ACCEPTANCE

This SMTA shall be a “click-wrap” arrangement if executed by electronic means, or a “shrink-wrap” agreement otherwise, unless either party requires this Agreement to be executed by signature of a printed document. All three methods are equally valid, binding and enforceable to confirm acceptance of this Agreement and only one method is required to establish acceptance.

The Provider and the Recipient may choose the method of acceptance unless either party requires this Agreement to be signed.

Option 1 – Acceptance by signature of printed document

I, (Full Name of Authorized Official), represent and warrant that I have the authority to execute this Agreement on behalf of the Provider and acknowledge my institution’s responsibility and obligation to abide by the provisions of this Agreement.

Signature..... Date.....

Name of the Provider.....

I, (Full Name of Authorized Official), represent and warrant that I have the authority to execute this Agreement on behalf of the Recipient and acknowledge my institution’s responsibility and obligation to abide by the provisions of this Agreement.

Signature..... Date.....

Name of the Recipient.....

Option 2 – Shrink-wrap Standard Material Transfer Agreements

The Material is provided conditional on acceptance of the terms of this Agreement.

The provision of the Material specified in Annex – by the Provider and the Recipient’s acceptance and use of the Material constitutes acceptance of the terms of this Agreement.

Option 3 – Click-wrap Standard Material Transfer Agreement

The Material is provided upon acceptance of this Agreement concluded through electronic means.

☐ *I hereby agree to the above conditions.*

White Paper 4

WHO European Region Proposal of an alternative Article 2¹ and an Annex to the Standards Terms and Conditions for Transfers of WHO PIP Materials:

(Version as of 12.5.2010; 10am)

2. Recipient of the WHO PIP Materials [shall]/ [are urged to]:
 - Participate in the solidarity mechanism as described in the annex
 - 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.
 - Continue to offer tiered pricing.

Annex:

The solidarity mechanism will be managed by WHO and consists of:

- (a) a contribution of 0.X % of revenues from the sale of seasonal vaccine and X % of revenues from the sales of pre- and/or pandemic vaccine, or
- (b) a combination of one or several of the following on the basis of a mutual arrangement between the recipient and WHO such as:
 - donation of pandemic vaccines
 - donation of pre-pandemic vaccines
 - transfer of technology
 - capacity building
 - granting of sublicenses to WHO
 - financial contribution to WHO pandemic preparedness and response activities
 - donation of antiviral and / or medical devices
 - logistics
 - support of surveillance systems

¹ Refers to article 2 of the Standard Terms and Conditions annexed to the SMTA proposal of the Co-chairs, as contained in White Paper 1, and would also correspond to Article 4 of SMTA2.

In the “Pandemic Influenza preparedness framework for the sharing of influenza viruses and access to vaccines and other benefits” a description of the following elements should be added:

- guiding principles to be applied by WHO in the negotiations with industry (what combination of technology transfer, donations and other elements should be aimed at)
- modalities of the management of the received finances within WHO under its rules
- how these activities are interacting / integrated with existing activities such as the GAP
- the role of voluntary contributions from Member States and other sources
- guiding principles of a mechanism for solidarity and equity of early access to pandemic vaccine¹

= = =

¹ This mechanism would enable, in time of a pandemic, to vaccinate essential healthcare workers (more or less 2 per cent of each country’s population), as soon as vaccines are available. First, WHO and manufacturers would assess global production capacity and the extent to which each manufacturer could contribute to the mechanism. Then, options should be explored in order to ensure equitable and timely access to vaccines from the start of a pandemic.

WHO would distribute these doses according to its assessment on the public health risks and needs.