World Health Organization

INTERGOVERNMENTAL MEETING ON PANDEMIC INFLUENZA PREPAREDNESS: SHARING OF INFLUENZA VIRUSES AND ACCESS TO VACCINES AND OTHER BENEFITS
OPEN-ENDED WORKING GROUP
Provisonal agenda item 3

A/PIP/IGM/WG/2
3 April 2008

Extracts from EB122/5

STANDARD TERMS AND CONDITIONS

This document contains extracts from the Intergovernmental Meeting's White Paper 3 (dated 21 November 2007). The passages may be found in the consolidated outcome text in document EB122/5, Annex 6, pages 31–100.

Key to document references:

IGM/2 Rev.1 refers to document A/PIP/IGM/2 Rev.1, Reports by the Director-General: Summary progress reports. (The document summarizes actions undertaken and planned in order to implement the following paragraphs of resolution WHA60.28: 2(1) on frameworks and mechanisms, 2(2) on establishing an international stockpile of vaccines, and 2(3) on mechanisms and guidelines for distributing vaccines fairly and equitably.)

IGM/4 refers to document A/PIP/IGM/4, Sharing of influenza viruses and access to vaccines and other benefits: Interdisciplinary Working Group on Pandemic Influenza Preparedness. (The meeting (Singapore, 31 July – 4 August 2007) was convened in accordance with resolution WHA60.28 (paragraph 2(5)) and the document contains a summary of the debate.)

IGM/5 refers to document A/PIP/IGM/5, Annex: Fundamental principles and elements for the development of a new system for virus access and fair and equitable benefit sharing arising from the use of the virus for the pandemic influenza preparedness. (This text was proposed by Indonesia to be considered as a working document for the discussion in the Intergovernmental Meeting on Pandemic Influenza Preparedness, 20–23 November 2007.)

IGM/6 refers to document A/PIP/IGM/6, Annex: A proposal from Thailand for the Intergovernmental Meeting on Pandemic Influenza Preparedness, 20–23 November 2007: Standard Terms and Conditions (STCs) for the transfer and use of influenza biological materials and fair and equitable benefits sharing (between Member States [MS] and WHO Secretariat [WS]).

AFRO refers to document A/PIP/IGM/7, Annex: Standard Terms and Conditions for the transfer and use of influenza biological materials and fair and equitable benefit sharing: A proposal from the African Region for the Intergovernmental Meeting on Pandemic Influenza Preparedness, 20–23 November 2007.

NOTES:

(1) Text **agreed** by consensus at the Intergovernmental Meeting is marked in ***bold, italics,*** followed by the word ***"agreed"*** in parenthesis. Only text marked in this manner was agreed by consensus at the Meeting.

(2) Submission of revised text from delegations to the Meeting is marked in *italics* with country/region attribution in parenthesis, in ***bold, italics***.

Footnotes appear at the **end** of the document.

In all cases, the **bold number** immediately following the document number refers to the paragraph in the document.

VIRUS SHARING

DEFINITION and SCOPE (Indonesia prefers the term Standard Material Transfer Agreement)

Insert definition of viruses and other materials ***(UK)*** *(to use text from the Glossary prepared by the Secretariat)*

[Access to virus is provided *for a timely vaccine production, including vaccine which will be made available for a vaccine stockpile* ***(Finland)*** The global stockpile should be formulated by WHO and endorsed by Member States. **(IGM/5 Fundamental Elements 1)]** *(to be reviewed under "Benefit Sharing")*

Viruses to be shared for surveillance and risk assessment, and production of vaccine, candidate influenza vaccine viruses (H5N1 and novel subtype) as well as development and validation of diagnostics (Norway) (to take text from WHA60.28 for the purpose of use of virus) (agreed)

One of the most important benefits derived from virus sharing is WHO's continued ability to assess the global risk of the emergence of a strain of influenza virus with pandemic potential, as required under the International Health Regulations (2005). This global public health benefit requires at a minimum: access to the broadest range of circulating influenza viruses; up-to-date influenza laboratories and specialists; and information systems to provide timely feedback to countries for response. The information derived from risk assessment enables the updating of vaccines, pharmaceuticals and diagnostic materials, all of which contribute to effective global responses to influenza outbreaks. WHO will continue to coordinate provision of this global public health benefit. (IGM/2 Rev.1) (agreed)

[All institutions in compliance with STCs and TORs (Chair's proposal) may continue to receive reagents and technical assistance from laboratories within the GISN] ***(USA electronic submission)***

[Manufacturers can only obtain [seed virus] *candidate influenza vaccine virus* (UK) from the system with [prior informed consent] of the originating country and [must commit to benefit sharing]]. **(IGM/5 Fundamental Elements 8)** *(to be discussed under STCs)*

[Access to specimen/virus must be done through an agreement in the form of a standard Material Transfer Agreement (MTA) agreed by Member States. **(IGM/5 Fundamental Elements 2)]** *(to be discussed under STCs)*

[Any use of virus outside the Terms of Reference must get prior informed consent from the originating country. **(IGM/5 Fundamental Elements 4)]**

[The virus accessed is to be used only for non-commercial risk assessment and response according to the Terms of Reference which is to be agreed. **(IGM/5 Fundamental Elements 3)]** *(to be discussed under STCs and TORs)*

[Virus samples are to pass into and out of the newly reformed/improved GISN that may be recommended, according to STCs and TORs to be agreed to by Member States. Recipients of a virus sample outside of the newly reformed/improved GISN are to pass the sample to another party/(third party) in accordance with these STCs and TORs.] ***(USA)***

The *originating country* agrees to provide to the *second party* ***(Thailand)*** certain materials (e.g. *human specimens and wild type viruses* ***(UK)*** *for the uses identified in the STCs.* ***(Thailand)*** **(IGM/6 3)** *(use text from the Glossary) (to be consistent with the Norway proposal above)*

The WHO Secretariat is to create an electronic tracking system to record the movements of all virus samples and vaccine candidate strains ***(USA electronic submission)***

[The country or institution of origin are to be notified/prior informed consent ***(Indonesia)*** *immediately of distribution of a virus sample outside of the GISN]* ***(USA electronic submission)***

Institutions inside and outside of GISN may use virus samples for risk assessment, vaccine development and public health oriented research (USA electronic submission), according to the STCs and TORs (Indonesia) (agreed)

The WHO Collaborating centres and other institutions that are the recipient of virus samples are to assure that appropriate laboratories in the country or institution of origin receive the results of risk assessment and copies of isolated virus strains and/or vaccine candidate strains on a timely basis (USA electronic submission) (agreed)

Recognizing the need for timely and continuous development of vaccines and anti-viral drugs effective against influenza virus, vaccine manufacturers in both developed and developing countries may obtain candidate vaccine strains free-of-charge from the newly reformed and improved [GISN] ***(USA electronic submission)/ [****prior informed consent]* ***(Indonesia)***

In addition, these STCs do not provide coverage for use of other agents or pathogens that may be contained in the materials, e.g. respiratory bacteria, non-influenza respiratory viruses. **(IGM/6 3)**

[These STCs are binding on all parties involved.] **(IGM/6 3)**

[All annexes form an integral part of these STCs.] **(IGM/6 3)**

EU Member States are open to consider what we think it would be an alternative option, that would be "to have two parties", but our main concern should be the leadership of WHO in order to ensure transparency and the right way to achieve this would be to have:

(1) a clear vision of all participants and of their relationship and functions;

(2) a definition of the number of partners and their TOR

In conclusion, we would like to request the WHO to issue a document describing the current stakeholders and framework for sharing viruses and to provide with several proposals on how to improve the system. The document could be the basis for further discussion and taking a decision. ***(EU submission)***

[STANDARD TERMS AND CONDITIONS FOR THE TRANSFER AND USE OF INFLUENZA BIOLOGICAL MATERIALS

Identification of Parties (IGM/6 2)

This is the STCs between Member States (MS) and the WHO Secretariat (WS) only. **(IGM/6 2)**

The Member States include only members of the WHO and shall be represented by an agency or unit or organization, as to be designated and notified to the WS in writing by the MS. **(IGM/6 2)**

The WHO Secretariat is represented by the Director-General (DG) and/or his/her designate(s). The DG of the WHO could designate, and publicly announce, one of his/her deputies or assistants or departments or units to act on his/her own behalf.

> *(Remark: Please note that this identification of parties is markedly different from previously-proposed STC because it limits the number of parties to only two. In addition, these STCs do not use the term "GISN", nor does it mention NICs, WHOCCs, WHOH5RLs, etc. The omission of these terms does not mean to undermine or diminish the importance of GISN and its members. The omission is done for the sake of simplicity and clarity. As a matter of fact, the NICs, WHOCCs, WHOH5RLs have well-defined TORs that could be easily agreed by MS. If the NICs, WHOCCs, and WHOH5RLs play their roles and do the functions as set forth in the TORs, the GISN as a whole will be strengthened automatically, without the need to include the term GISN and the TORs of these GISN-associated entities in these STCs.)* **(IGM/6 2)**

Rights and Responsibilities of all Parties

Authority to determine access to influenza viruses rests within the national government and subject to national laws. **(IGM/6 4)**

Access to specimen/virus must be done through an agreement in the form of a standard Material Transfer Agreement (MTA) agreed by Member States. **(IGM/6 2)**

Subsequent transfer of the virus can be done only with the prior informed consent of the originating country. **(IGM/6 5)**

If a subsequent recipient of materials from the WS does not comply with these STCs, the MS, individually or collectively, and/or the WS have the right to deny the recipient with new materials as appropriate. **(IGM/6 8**)

Originating Countries (Member States)

The MS shall provide to the WS or other WS-designated entity the materials that may contain influenza virus or part thereof or antibody to the virus as soon as possible without request from the WS. The provision may be accompanied by a cover letter indicating that such provision is automatically covered by these STCs. **(IGM/6 11)**

If there is a good reason to believe that the WS or any of entities that receive the influenza virus or part thereof or antibody to the virus does not comply with these STCs, the concerned MS(s) has the right to deny the WS or the entity/-ties with the new materials. In addition, the MS(s) may request the

Oversight Mechanism to investigate the incident(s) that may be associated with such non-compliance. **(IGM/6 11)**

The MS has the right to access, at no cost, to information related to influenza virus or part thereof or antibody to the virus, as generated by the WS or any of the entities that subsequently receive the virus or the antibody. **(IGM/6 11)**

The MS has the right to receive, at no cost, all outputs of activities undertaken in relation to the materials provided to the WS or any WS-designated entity including influenza viruses isolated from the materials and sequence data of the influenza viruses. **(IGM/6 11)**

The MS has the right to provide the materials under these STCs to any other non-WS-associated entity/-ties on a bilateral or multilateral basis provided that such provision does not deprive the WS of the right to receive the same under these STCs. **(IGM/6 11)**

The MS has the obligations to strengthen its surveillance and risk assessment system to be able to early and accurate detection of influenza outbreaks. **(IGM/6 11)**

The MS has the obligations to contribute to the Global Influenza Vaccine Fund (GIVF – *pronounced "give"*). **(IGM/6 11)**

The originating country providing access to virus: (1) retains sovereign rights over the virus and any virus material contained or incorporated in any substances or products created; (2) has the right to get immediately the results of the risk assessment; (3) has the right to timely receive seed virus and isolated virus at no cost; (4) has the right to participate in the execution of research and participate actively in publications; and (5) has the right to be adequately acknowledged. **(IGM/5 Fundamental Elements 6)**

Rights and Obligations of the WHO (WS)

The WS has the right to designate any entity within or outside its organization to receive the materials under these STCs, provided that: **(IGM/6 12)**

(i) such designation is made in writing **(IGM/6 12)**

(ii) the use of the materials is consistent with these STCs **(IGM/6 12)**

(iii) there is a written agreement for each transaction of transfer of the materials or products made out of the materials **(IGM/6 12)**

(iv) the transaction of transfer of materials is recorded in the real-time tracking system of the WS that is publicly accessible **(IGM/6 12)**

(v) the recipient of the materials agrees in writing not to subsequently transfer of the materials to any other entity **(IGM/6 12)**

(vi) the recipient of the materials agrees in writing to contribute to the Global Influenza Vaccine Fund (GIVF) **(IGM/6 12)**

(vii) the recipient of the materials agrees in writing to participate fully in the Global Influenza Vaccine Benefits Sharing Scheme (GIVBeSS – *pronounced "give bes(t)"*) **(IGM/6 12)**

(viii) the recipient of the materials agrees in writing not to seek or assert intellectual rights or other rights over substances, processes, products including vaccines, anti-virals, diagnostics or any other inventions derived from the materials, developed through the use or that contain and/or incorporate the materials. **(IGM/6 12)**

The WS shall ensure that, if the recipients of the materials from the WS wish to transfer the materials subsequently to another recipient or recipients, these STCs shall apply and the subsequent transfer of the materials needs prior approval from the WS and is considered "executed by the WS". **(IGM/6 12)**

The WS and the recipient of the materials through the WS has the right to publish sequence data of the viruses obtained from the MS under these WS in a public-domain database provided that: **(IGM/6 12)**

(i) the WS clearly indicates in the intended publication that such publication is covered by these STCs and use of the publicized data shall be consistent with these STCs **(IGM/6 12)**

(ii) the MS is properly acknowledged in such intended publication **(IGM/6 12)**

(iii) the MS is notified in writing of such intended publication**(IGM/6 12)**

(iv) the MS does/do not object to such intended publication within 14 days of receipt of such written notification. **(IGM/6 12)**

The WS and the recipient of the materials through the WS has the right to present, publish or otherwise disseminate scientific results generated from the materials provided that: **(IGM/6 12)**

(i) the WS clearly indicates in the presentation, publication or dissemination that such presentation, publication, and dissemination are covered by these STCs **(IGM/6 12)**

(ii) the MS and its scientists and/or researchers are properly acknowledged or included as co-authors in the manner that is consistent with the guidelines for authorship and acknowledgement stipulated in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals **(IGM/6 12)**

(iii) the MS is notified in writing of such intended presentation, publication, or dissemination **(IGM/6 12)**

(iv) the MS does/do not object to such intended presentation, publication, and dissemination within 14 days of receipt of such written notification. **(IGM/6 12)**

If the materials provided to the WS by the MS have led to a product or products (e.g. candidate vaccine virus, vaccine seed) that may be used to production of an influenza vaccine, the WS has the obligations to obtain a written agreement from the recipient of the materials that manufacturers of the vaccine or product agree in writing to contribute to the GIVF and the GIVBeSS. **(IGM/6 12)**

The WS has the obligations to develop, within 180 days after these STCs are approved by the World Health Assembly, a real-time tracking system for the materials provided under these STCs and derivatives and products made out of the materials. **(IGM/6 12)**

The WS has the obligations to develop, together with MS the GIVF and the GIVBeSS. **(IGM/6 12)**

The WS has the obligations to develop, within 180 days after these STCs are approved by the World Health Assembly, an electronic system that renders material transfer agreements between the WS and the recipients of the materials publicly available and accessible within 3 days of execution of the agreements. **(IGM/6 12)**

The WS has the obligations to respond to the inquiry and request from the MS as stipulated in these STCs. **(IGM/6 12)**

Upon request by the MS, the WS shall arrange return or destruction of the materials provided to the WS by the MS without delay. **(IGM/6 10)**

Sequence data must be placed in a database only with the prior informed consent of the originating country. The database will be governed by rules and regulations to prevent misappropriation. **(IGM/5 Fundamental Elements 7)**

Rights and obligations of other parties

General Provisions

Safety: All parties shall ensure that all transfers under these STCs will at all times be in compliance with all relevant national and international laws, rules, and regulations governing the handling, safe transfer and use of infectious substances and living microorganisms. **(IGM/6 4)**

Warranty: All materials delivered pursuant to these STCs are understood to be experimental in nature and may have hazardous properties. They are provided to recipients without any representation and extends no warranties whatsoever, either express or implied, as to their quality, viability, purity, merchantability, suitability or fitness for a particular purpose or that its use will not infringe any patent, copyright, trademark, or other propriety right. **(IGM/6 4)**

Indemnity: Recipients of materials shall assume all liability for any claims, costs, damages or expenses resulting from or otherwise related to the possession and use of the materials. The MS will not be liable for any loss, claim or demand made to or arising from the use, storage or disposal of the materials. **(IGM/6 4)**

Applicable Law: The applicable law shall be _____. **(IGM/6 4)**

Dispute Settlement: Dispute settlement may be initiated by the MS or the WS in relation to their respective relationships in the context of these STCs. Any dispute arising from these STCs shall be resolved through the Oversight Mechanism to be established by the WS and agreed by the MS in a World Health Assembly. **(IGM/6 4)**

Termination

When one of the parties fails to fulfil its obligations or violates any of these STCs and the aggrieved party has given the other party notice of not less than 30 days in writing requiring that the failure or violation be remedied. If the failure or violation is not remedied within the said 30 days, the aggrieved party shall have the right to terminate these STCs. **(IGM/6 5)**

Upon termination, the WS shall immediately arrange discontinuation of any use of the materials in any manner including either derivation or development of substances, processes, products from the materials, and shall arrange the return or the destruction of any remaining materials. **(IGM/6 4)**

Termination of these STCs shall not affect the accrued rights and obligations that were due prior to the effective date of termination of these STCs. **(IGM/6 4)**

With regard to termination of these STCs, each Member State constitutes one party to the STCs. **(IGM/6 4)**

Notices

Any notices or requests to be made under these STCs shall be in writing and shall, except where it is otherwise stated, be delivered by courier, or by facsimile, or by electronic mail, to the address of the entity to be designated by each party, and shall be deemed to have been received on the date of delivery, if delivered by courier, and on the first business day following the electronic confirmation of the successful transmission of the facsimile or electronic mail, if sent by facsimile or electronic mail. **(IGM/6 6)**

Duration of Agreement

These STCs shall remain in force until otherwise determined by a World Health Assembly. **(IGM/6 7)**

VIRUS TRACKING SYSTEM

WHO shall develop a database accessible to Member States to track movement of all viruses and seed viruses. **(IGM/5 Fundamental Elements 12)**

The WS shall establish a tracking system and database for transfer and movement of materials and their derivatives (including but not limited to throat, nasal, nasopharyngeal, and other swabs; blood or parts thereof; viral isolates and parts thereof including genetic characteristics, biological characteristics, clones, plasmids, and recombinants) on a real-time basis. **(IGM/6 9)]**

APPENDIX

STANDARD TERMS AND CONDITIONS FOR THE TRANSFER AND USE OF INFLUENZA BIOLOGICAL MATERIALS

Identification of Parties (IGM/6 2)[1] [Note from the Secretariat: See page 96]

This is the STCs between Member States (MS) and the WHO Secretariat (WS) only. **(IGM/6 2)**

The Member States include only members of the WHO and shall be represented by an agency or unit or organization, as to be designated and notified to the WS in writing by the MS. **(IGM/6 2)**

The WHO Secretariat is represented by the Director General (DG) and/or his/her designate(s). The DG of the WHO could designate, and publicly announce, one of his/her deputies or assistants or departments or units to act on his/her own behalf.

(Remark: Please note that this identification of parties is markedly different from previously-proposed STC because it limits the number of parties to only two. In addition, these STCs do not use the term "GISN", nor does it mention NICs, WHOCCs, WHOH5RLs, etc. The omission of these terms does not mean to undermine or diminish the importance of GISN and its members. The omission is done for the sake of simplicity and clarity. As a matter of fact, the NICs, WHOCCs, WHOH5RLs have well-defined TORs that could be easily agreed by MS. If the NICs, WHOCCs, and WHOH5RLs play their roles and do the functions as set forth in the TORs, the GISN as a whole will be strengthened automatically, without the need to include the term GISN and the TORs of these GISN-associated entities in these STCs.) **(IGM/6 2)**

OR

1. The parties are: **(AFRO Region B1**)

   (a) **First Party:** The State or national entity/ies designated and authorised by the State to provide Original Specimens on its behalf**. (AFRO Region B1)**

   (b) **Second Party:** Any of the following as applicable, which undertake non commercial activities according to their Terms of References under the [New Framework for Virus Sharing and Benefit Sharing of the WHO] **(AFRO Region B1)**:

      (i) WHO Collaborating Centres for Reference and Research on Influenza that have satisfied WHO criteria for designation and have accepted the Terms of Reference attached in Annex 3; **(AFRO Region B1)**

      (ii) WHO H5 Reference Laboratories (hereinafter referred to as "H5RLs") that have satisfied WHO criteria for designation and that have accepted the Terms of Reference attached in Annex 4[1]; **(AFRO Region B1)**

[1] As of …. The H5RL are as follows: ……..

(c) **Third Party:** Institutions/Organisations/Companies that develop and produce Influenza Vaccines and that are approved by WHO to receive Biological Materials for Development as defined below. *(cf. para 3 (b) (c) Sect. STC)* **(AFRO Region B1**)

(d) **The World Health Organization** (hereinafter referred to as "WHO") **(AFRO Region B1**)

OR

The parties include: **(IGM/4 Section B)**

First party: [USA: The United States proposed that we should only refer to this entity as the "First Party" to avoid confusion.], is the State or national entity (NIC or non-NIC) that provides the Specimens. **(IGM/4 Section B)**

(i) "National Influenza Centres" (NICs): National influenza reference laboratories that have been designated by a Ministry of Health and recognized by WHO under defined TORs. **(IGM/4 Section B)**

(ii) "Non-NICs": laboratories designated by a government, that comply with the same TOR as NICs. **(IGM/4 Section B)**

Second party: "Second Party" is WHO, of which GISN is a programme activity implemented with the following partners:

(i) WHO Collaborating Centres for Reference and Research on Influenza (WHO CC): influenza centres of excellence that have satisfied WHO criteria for designation and have accept defined Terms of Reference (TORs). [Thailand: It should be made clear that St Jude's Hospital is one of the Third Parties, not one of the Second Parties, in this STCs.] **(IGM/4 Section B)**

(ii) WHO H5 Reference Laboratory (H5RL): an influenza laboratory that has been designated by WHO to fulfill the defined TORs that bridge the gap in H5 diagnostic capacity worldwide. **(IGM/4 Section B)**

(iii) Essential national regulatory laboratories: specialized government laboratories involved in WHO influenza vaccine selection and development process;

(iv) Laboratories involved in specific WHO influenza projects (e.g. WHO Polymerase chain reaction (PCR) working group, WHO External Quality Assurance Project (EQAP)).] [UK: The following sentence seems redundant. Second party is WHO, or entities recognized as designated by WHO, as represented by WHO GIP; WHO CCs, essential national regulatory lab] **(IGM/4 Section B)**

Third party includes but is not limited to influenza vaccine manufacturers, commercial research laboratories and [diagnostic companies], that request and receive GISN Biological Materials or parts thereof. [UK: We understood that GISN Biological Materials would be changed throughout to Biological Materials] **(IGM/4 Section B)**

Rights and Responsibilities of all Parties[2] [Note from the Secretariat: See page 96]

Authority to determine access to influenza viruses rests within the national government and subject to national laws. **(IGM/6 4)**

Access to specimen/virus must be done through an agreement in the form of a standard Material Transfer Agreement (MTA) agreed by Member States. **(IGM/6 2)**

Subsequent transfer of the virus can be done only with the prior informed consent of the originating country. **(IGM/6 5)**

If a subsequent recipient of materials from the WS does not comply with these STCs, the MS, individually or collectively, and/or the WS have the right to deny the recipient with new materials as appropriate. **(IGM/6 8)**

Originating Countries (Member States)[3] [Note from the Secretariat: See page 96]

The MS shall provide to the WS or other WS-designated entity the materials that may contain influenza virus or part thereof or antibody to the virus as soon as possible without request from the WS. The provision may be accompanied by a cover letter indicating that such provision is automatically covered by these STCs. **(IGM/6 11)**

If there is a good reason to believe that the WS or any of entities that receive the influenza virus or part thereof or antibody to the virus does not comply with these STCs, the concerned MS(s) has the right to deny the WS or the entity/-ties with the new materials. In addition, the MS(s) may request the Oversight Mechanism to investigate the incident(s) that may be associated with such non-compliance. **(IGM/6 11)**

The MS has the right to access, at no cost, to information related to influenza virus or part thereof or antibody to the virus, as generated by the WS or any of the entities that subsequently receive the virus or the antibody. **(IGM/6 11)**

The MS has the right to receive, at no cost, all outputs of activities undertaken in relation to the materials provided to the WS or any WS-designated entity including influenza viruses isolated from the materials and sequence data of the influenza viruses. **(IGM/6 11)**

The MS has the right to provide the materials under these STCs to any other non-WS-associated entity/-ties on a bilateral or multilateral basis provided that such provision does not deprive the WS of the right to receive the same under these STCs. **(IGM/6 11)**

The MS has the obligations to strengthen its surveillance and risk assessment system to be able to early and accurate detection of influenza outbreaks. **(IGM/6 11)**

The MS has the obligations to contribute to the Global Influenza Vaccine Fund (GIVF – *pronounced "give"*). **(IGM/6 11)**

The originating country providing access to virus: (1) retains sovereign rights over the virus and any virus material contained or incorporated in any substances or products created; (2) has the right to get immediately the results of the risk assessment; (3) has the right to timely receive seed virus and

isolated virus at no cost; (4) has the right to participate in the execution of research and participate actively in publications; and (5) has the right to be adequately acknowledged. **(IGM/5 Fundamental Elements 6)**

OR

Rights And Responsibilities Of The First Party (Afro Section F)

1. The First Party retains sovereign rights (including the authority to determine access and therefore the terms of the access) to the Biological Material including any Biological Material contained or incorporated in any substances or products created by the Second and Third Parties respectively. **(AFRO Section F)**

2. The First Party shall ensure that documentation accompanying the Original Specimen includes a duly completed Implementing Letter attached in Annex 1 signed by all Parties, properly identifying the "Original Specimen", a copy of the STC and a traceability number. A copy of the signed Implementing Letter shall be sent to the WHO. **(AFRO Section F)**

3. The First Party shall on delivery of the Original Specimen enter all information in relation to the Original Specimen required into a common database (minimal dataset) that is to be developed by the WHO. **(AFRO Section F)**

5. Original Specimen is to be provided by the First Party to the Second Party at no cost or at an optional transmittal fee to reimburse the First Party on request, for costs of shipping, handling, storage or other direct administrative overheads in preparation of sending the Original Specimen to the Second Party. If the First Party requests transmittal fee, the amount will be indicated in the Implementing Letter. **(AFRO Section F)**

6. The First Party shall establish a focal point for purposes of communication under the STC and provide all the relevant contact details of the focal point to the WHO. The focal point will be the official authorised to sign the Implementing Letter on behalf of the First Party. **(AFRO Section F)**

OR

Rights And Responsibilities Of The First Party [Germany: In The Following, Only Responsibilities Are Listed, But No Rights – Change Title?] (IGM/4 Section E)

1. The First Party shall ensure that the ~~S~~specimens are handled, packed and shipped to a WHO CC of its choice in a timely [USA: See note above regarding the definition of timely] manner in accordance with applicable national and international regulations on the shipment of Infectious Substances. Documentation accompanying Specimens shall properly identify the "Specimens", and include a traceability[Canada]/tracking[USA] number, as well as a copy of these STCs, and a Specimen submission form signed by the First Party. [UK: We believe that it should be a responsibility of the First Party to ensure as far as possible the integrity of the sample (i.e. that it contains useful infectious material). There should be an SOP to cover this.] **(IGM/4 Section E)**

2. (new para) First Party shall enter information/identification of the Specimen into a common database (minimal dataset), that the WHO Secretariat will develop, along with a system to track viruses through the GISN system. **(IGM/4 Section E)**

Rights and Obligations of the WHO (WS)[4] [Note from the Secretariat: See page 97]

The WS has the right to designate any entity within or outside its organization to receive the materials under these STCs, provided that: **(IGM/6 12)**

(i) such designation is made in writing **(IGM/6 12)**

(ii) the use of the materials is consistent with these STCs **(IGM/6 12)**

(iii) there is a written agreement for each transaction of transfer of the materials or products made out of the materials **(IGM/6 12)**

(iv) the transaction of transfer of materials is recorded in the real-time tracking system of the WS that is publicly accessible **(IGM/6 12)**

(v) the recipient of the materials agrees in writing not to subsequently transfer of the materials to any other entity **(IGM/6 12)**

(vi) the recipient of the materials agrees in writing to contribute to the Global Influenza Vaccine Fund (GIVF) **(IGM/6 12)**

(vii) the recipient of the materials agrees in writing to participate fully in the Global Influenza Vaccine Benefits Sharing Scheme (GIVBeSS – *pronounced "give bes(t)"*) **(IGM/6 12)**

(viii) the recipient of the materials agrees in writing not to seek or assert intellectual rights or other rights over substances, processes, products including vaccines, anti-virals, diagnostics or any other inventions derived from the materials, developed through the use or that contain and/or incorporate the materials. **(IGM/6 12)**

The WS shall ensure that, if the recipients of the materials from the WS wish to transfer the materials subsequently to another recipient or recipients, these STCs shall apply and the subsequent transfer of the materials needs prior approval from the WS and is considered "executed by the WS". **(IGM/6 12)**

The WS and the recipient of the materials through the WS has the right to publish sequence data of the viruses obtained from the MS under these WS in a public-domain database provided that: **(IGM/6 12)**

(i) the WS clearly indicates in the intended publication that such publication is covered by these STCs and use of the publicized data shall be consistent with these STCs (IGM/6 12)

(ii) the MS is properly acknowledged in such intended publication (IGM/6 12)

(iii) the MS is notified in writing of such intended publication (IGM/6 12)

(iv) the MS does/do not object to such intended publication within 14 days of receipt of such written notification. **(IGM/6 12)**

The WS and the recipient of the materials through the WS has the right to present, publish or otherwise disseminate scientific results generated from the materials provided that: **(IGM/6 12)**

(i) the WS clearly indicates in the presentation, publication or dissemination that such presentation, publication, and dissemination are covered by these STCs **(IGM/6 12)**

(ii) the MS and its scientists and/or researchers are properly acknowledged or included as co-authors in the manner that is consistent with the guidelines for authorship and acknowledgement stipulated in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals **(IGM/6 12)**

(iii) the MS is notified in writing of such intended presentation, publication, or dissemination **(IGM/6 12)**

(iv) the MS does/do not object to such intended presentation, publication, and dissemination within 14 days of receipt of such written notification. **(IGM/6 12)**

If the materials provided to the WS by the MS have led to a product or products (e.g. candidate vaccine virus, vaccine seed) that may be used to production of an influenza vaccine, the WS has the obligations to obtain a written agreement from the recipient of the materials that manufacturers of the vaccine or product agree in writing to contribute to the GIVF and the GIVBeSS. **(IGM/6 12)**

The WS has the obligations to develop, within 180 days after these STCs are approved by the World Health Assembly, a real-time tracking system for the materials provided under these STCs and derivatives and products made out of the materials. **(IGM/6 12)**

The WS has the obligations to develop, together with MS the GIVF and the GIVBeSS. **(IGM/6 12)**

The WS has the obligations to develop, within 180 days after these STCs are approved by the World Health Assembly, an electronic system that renders material transfer agreements between the WS and the recipients of the materials publicly available and accessible within 3 days of execution of the agreements. **(IGM/6 12)**

The WS has the obligations to respond to the inquiry and request from the MS as stipulated in these STCs. **(IGM/6 12)**

Upon request by the MS, the WS shall arrange return or destruction of the materials provided to the WS by the MS without delay. **(IGM/6 10)**

Sequence data must be placed in a database only with the prior informed consent of the originating country. The database will be governed by rules and regulations to prevent misappropriation. **(IGM/5 Fundamental Elements 7)**

OR

Responsibilities Of The WHO (AFRO Section I)

(1) The WHO shall prior to granting approval to the request of the Third Party for Biological Materials for Development obtain the prior written consent of the First Party. **(AFRO Section I)**

(2) The WHO shall enter all information concerning the transfer of Biological Materials for Development to the Third Party into the WHO tracking database. **(AFRO Section I)**

(3) The WHO shall develop a database for the NFVSBS to track movement of all the Biological Material, CIVV and Biological Materials for Development, throughout the New Framework. **(AFRO Section I)**

(4) The WHO shall develop a database for the deposit of sequence data under the STC. Access to the database shall only be allowed to entities, organisations and companies that agree to terms and conditions that are to be developed. **(AFRO Section I)**

(6) The WHO shall take all measures necessary to ensure compliance by the Third Party of its obligations under the STC, in particular the benefit sharing obligations. WHO shall issue a biannual report on measures taken and mechanisms established to implement the benefit sharing obligations by Third Parties and the results of benefit sharing as well as the challenges faced in implementation. **(AFRO Section I)**

Rights And Responsibilities Of The Second Party (AFRO Section G)

1. Permitted Uses

(a) The Second Party shall use the Biological Material, solely for purposes listed in the Terms of Reference in Annex 3 where the Second Party is a WHO CC, or for purposes listed in the Terms of Reference in Annex 4 where the Second Party is a H5RL. *(cf. para 18 Sect. STC)* **(AFRO SECTION G)**

(b) The Second Party shall use the Biological Material only at the Second Party's facility. **(AFRO SECTION G)**

(c) The Second Party may transfer the Biological Material and/or CIVV to another Recipient Second Party only with the prior written consent of the First Party. The Second Party shall advise the Recipient Second Party that it shall be bound by the terms of the STC. The Recipient Second Party agrees that the First Party has the right to take appropriate action against the Recipient Second Party as allowed by the STC. **(AFRO SECTION G)**

(d) The Second Party shall transfer at no cost to the Third Party only Biological Materials for Development as authorized by the WHO for transfer to the Third Party on receipt from WHO of a duly completed and signed Request Form/Implementing Letter,. **(AFRO SECTION G)**

(e) The Second Party shall not transfer by any means, either intentionally or accidentally, the Biological Material, substances or any product derived from the Biological Material or any other substances and products developed through the use of or that contains/incorporates the Biological Material such as CIVV to any other party except in accordance with the Terms of Reference in Annex 3 and 4 as applicable and the STC. **(AFRO SECTION G)**

(f) Any transfer of Biological Materials for Development in response to receipt of a duly completed and signed Request Form/Implementing shall be clearly labelled as "New Framework Biological Materials for Development" and a copy of the Request Form/Implementing Letter & the STC shall be included in the shipping documents. **(AFRO SECTION G)**

(g) For any uses of the Biological Material outside the scope of the STC and the respective Terms of Reference in Annex 3 and Annex 4, the Second Party shall refer to the First Party for

its prior written consent. Such activities are subject to mutually agreed terms. *(cf. para 23 Sect. STC)* **(AFRO SECTION G)**

(h) The Second Party shall not seek to derive any financial gain from use in any way of the Biological Material and other related information including from substances or any product derived from the Biological Material or any other substances and products developed through the use of or that contains/incorporates the Biological Material such as CIVV. *(cf. para 18 Sect. STC)* **(AFRO SECTION G)**

2. Reporting & Access to Research Output and Results by WHO and the First Party (AFRO SECTION G)

(a) The Second Party shall provide to the First Party and to WHO, information as stated in the Terms of References as annexed to the STC as soon as it is available, but no later than fourteen (14) days of obtaining the information *(cf. para 19 Sect. STC)* **(AFRO SECTION G)**

(b) The Second Party shall on request provide at no cost to the First Party all outputs from activities undertaken in relation to the Biological Material including viruses isolated from the Original Specimen, provided by the First Party. **(AFRO SECTION G)**

(c) The Second Party shall provide as soon as available and in confidence only to the First Party all sequence data derived from the Research conducted. **(AFRO SECTION G)**

3. Sequence Data (AFRO SECTION G)

(a) The Second Party shall obtain prior written consent of the First Party before placing any sequence data in any databases. Unless otherwise specified by the First Party, when written consent is given, the Second Party shall within 14 days post the sequence data into [WHO] Regulated Database. **(AFRO SECTION G)**

4. Intellectual Property Rights (AFRO SECTION G)

(a) The Second Party shall not seek or assert intellectual property rights or other rights over the Biological Material in any form. *(cf. para 18 Sect STC)* **(AFRO SECTION G)**

(b) The Second Party shall not seek or assert intellectual property rights or other rights over any substances, processes, products including vaccines, anti-virals, diagnostics and biological derived from the Biological Material, developed through the use of or that contain/incorporate the Biological Material. **(AFRO SECTION G)**

5. Publications, Empowerment & Capacity Building (AFRO SECTION G)

(a) The Second Party shall obtain prior written consent of the First Party, before using of any data, results, or concepts obtained from use of and/or analysis of the Biological Material, in presentations, abstracts, agreements, publications (both peer-reviewed and not peer-reviewed), grant applications or other means of dissemination. **(AFRO SECTION G)**

(b) The Second Party shall properly attribute in presentations, publications, agreements, grant applications and other means of dissemination, the source of the Biological Material, the name and contributions of the scientists and/or researchers and/or laboratories from the First Party.

Proper attribution of First Party scientists in any medical or scientific journal publication should be done in a manner that is consistent with the guidelines for authorship and acknowledgement stipulated by the International committee of Medical Journal Editors in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. *(cf. para 5(f) of the WHA60.28)* **(AFRO SECTION G)**

(c) The Second Party shall involve scientists from the First Party in the execution of the research and drafting as well as finalization of the publication. **(AFRO SECTION G)**

(d) The Second Party shall allow access to, and transfer, of technology and know how to the First Party, such as technology and know how to identify, characterize and monitor the influenza viruses, new technologies in identification of disease etiologies, and genetic analyses and shall endeavor to empower and build capacity as requested by the First Party or as stated in the Terms of Reference as annexed in the STC. **(AFRO SECTION G)**

6. Non-Assignment or Transfer of Rights (AFRO SECTION G)

The Second Party shall not assign or otherwise transfer this STC or any rights and obligations under this STC. Any attempted assignment or transfer will be void and of no force or effect. **(AFRO SECTION G)**

OR

Rights and Responsibilities of Second Party [Germany: same comment as above](IGM 4 Section F)

1. Second Party partners receiving, handling or using Biological Materials in their GISN capacity shall use the materials solely in accordance with their GISN TORs, and shall neither seek Intellectual property rights [UK: We disagree on this point. We do not believe it will always be in the interests of the network and Member States as a community to prevent development of IPR rights. There are circumstances in which this could be helpful. In any case, for tidiness, would seem that this point should be dealt with under Ownership and IPR Section.] nor seek to derive financial gain from their use. More specifically, Second Party partners shall not sell, offer for sale or otherwise use for purposes other than those specified in their TORs. [USA: We pointed out the redundancy here.]

2. Second Party partner shall provide the First Party with all necessary information for Risk Assessment derived from their analysis of the Specimens, as soon as possible, as more specifically detailed in the GISN TORs.

3. Second Party partners may transfer Biological Materials [USA: Specifically we need to clarify the definition of biological materials.] to other entities within the Second Party partner and from Second Party partner to First Party for use in accordance with these STCs, and applicable GISN TORs.

4. (new para) WHO shall develop a database for the GISN to track movement of all viruses throughout the GISN system. [USA: Redundant – see para 17.] The Second Party partner shall be responsible for entering data on virus movements into the database.

5. The Second Party partner shall consider ways to promote the involvement, participation and recognition of scientists from the First Party in research related to influenza, and shall properly attribute scientists from the First party in scientific publications through citation of the submitting

scientist's name and source country on any medical or scientific journal publication, consistent with rules for authorship outlined by the International Committee of Medical Journal Editors.

6. Use or transfer of Biological Materials by a Second Party partner for a purpose, or in a manner, outside the scope of the Second Party partner TORs shall require prior agreement of the First Party. [UK: The impact of this clause depends entirely on what the TORs specify. At present there are no TORs for the non-essential labs, which represent the main interface with vaccine manufacturers. Any requirement for prior agreement from First Parties for transfer of individual vaccine candidate strains to manufacturers would be very damaging to the ability to respond rapidly.][USA: Strike this entire paragraph].

7. Use or transfer of Biological Materials by the Second Party partner for a purpose, or a manner, inconsistent with these STCs or applicable TORs, may subject the Second Party partner to investigation under the GISN Oversight Mechanism if a Member State so requests or if routine monitoring reviews so warrant.

Rights and obligations of other parties

Rights And Responsibilities Of The Third Parties (AFRO Section H)

1. Request for Biological Materials (AFRO SECTION H)

(a) A Third Party that wishes to request Biological Materials for Development shall do so by completing and signing the Request Form & Implementing Letter attached in Annex 2, and sending it to the WHO for consideration, with a copy to the First Party. The Third Party shall identify the specific Biological Material for Development requested and state in detail the purpose for which it intends to use each specific material requested. *(Source: para 26 Sect. STC)* **(AFRO SECTION H)**

(b) The Third Party shall have the right to receive/access Biological Materials for Development from the Second Party which are authorized by the WHO. Where the Request Form & Implementing Letter is duly completed and signed by all parties, the Third Party will be bound by the STC. *(cf. para 26 Sect. STC)* **(AFRO SECTION H)**

2. Permitted Use (AFRO SECTION H)

(a) The Third Party will use the Biological Materials for Development received and any part thereof, solely for the purpose approved on the Request Form & Implementing Letter and for no other purpose. *(cf. para 28 Sect STC* **(AFRO SECTION H)***)*

(b) The Third Party shall not transfer the Biological Materials for Development or any part thereof by any means either intentionally or accidentally to any other party including other entities, organisations and companies. **(AFRO SECTION H)**

3. Intellectual Property Rights (AFRO SECTION H)

(a) The Third Parties shall not seek or assert intellectual property rights or other rights on the Biological Materials for Development received or any part thereof, in any form. *(cf. para 30 Sect. STC* **(AFRO SECTION H)***)*

(b) The Third Party shall not seek or assert intellectual property rights or other rights over any substances, processes, products including vaccines, anti-virals, diagnostics or any other inventions derived from the Biological Materials for Development, developed through the use of or that contain and/or incorporate the Biological Materials for Development. **(AFRO SECTION H)**

4. Service Providers (AFRO SECTION H)

(a) Third Party shall bring to the notice of any providers to it of services related to the development and production of vaccines, the terms and conditions contained herein and shall ensure full compliance by the providers with the STC. The Third Party agrees to take full responsibility and liability for any violation of the terms and conditions contained herein, by the providers of service. **(AFRO SECTION H)**

5. Publication, Empowerment & Capacity Building (AFRO SECTION H)

(a) The Third Party, its scientists and/or researchers will properly attribute in presentations, publications, agreements, grant applications and other means of dissemination, the source of the Biological Materials for Development and the Biological Material contained therein, the name and contributions of the scientists and/or researchers and/or laboratories from the First Party and Second Party. Proper attribution of First Party and Second Party scientists in any medical or scientific journal publication should be done in a manner that is consistent with the guidelines for authorship and acknowledgement stipulated by the International Committee of Medical Journal Editors in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. *(cf. para 29 Sect. STC)* **(AFRO SECTION H)**

(b) The Third Party will also include the First Party's scientists in the, execution of the research and the drafting as well as finalization of the publication. **(AFRO SECTION H)**

(c) The Third Party shall empower and build capacity of domestic manufacturers of the First Party and shall, on request build capacity and allow domestic manufacturers of the First Party to participate in the activities of the Third Party in relation to the Biological Materials for Development. **(AFRO SECTION H)**

6. Benefit Sharing (AFRO SECTION H)

(a) Royalty Free Licences, Transfer of Technology & Know-How (Source: Sect STC/ Indonesia Proposal) **(AFRO SECTION H)**

(i) The Third Party will grant on request, a non-exclusive, royalty-free license to any domestic influenza vaccine manufacturer from developing and least developed countries in particular to the First Party 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 pre-pandemic and pandemic vaccines. **(AFRO SECTION H)**

(ii) The Third Party will on request allow access to and transfer of its technology, know-how, all information and knowledge used in the process of influenza vaccine development and production as well as provide the necessary capacity building, to domestic influenza vaccine manufacturers from developing and least developed countries

in particular to the First Party in order to encourage domestic manufacturing of influenza vaccines in developing and least developed countries particularly pre-pandemic and pandemic vaccines, to fulfil domestic and regional needs.

(iii) In relation to (ii) the Third Party will provide the access and transfer at no cost [or on terms which are reasonable and favourable to developing countries in particular to the First Party] **(AFRO SECTION H)**

(b) Pandemic & Pre-pandemic Vaccines (Source: Sect STC/Indonesia proposal) **(AFRO SECTION H)**

(i) During the pre-pandemic the Third Party shall priorities and immediately respond to the demands of the WHO international stockpile and the demands of developing and least developed countries in need in particular that of the First Party until the needs for pre-pandemic vaccines are satisfied. X% of every vaccine production cycle, will be provided free of charge to the WHO international stockpile prior to commercialisation, while the rest of the vaccines needed by the WHO stockpile and the developing and least developed countries shall be made available immediately, in adequate quantities and at an affordable price. **(AFRO SECTION H)**

(ii) In the pandemic period, the Third Party shall prioritize and immediately respond to the demands of the WHO international stockpile and the demands of developing countries and least developed countries in need in particular the First Party until the needs for pandemic vaccines are satisfied. X% of every vaccine production cycle, will be provided free of charge to the WHO international stockpile prior to commercialisation, while the rest of the vaccines needed by the WHO stockpile and the developing and least developed countries shall be made available immediately, in adequate quantities and at an affordable price. **(AFRO SECTION H)**

[The Third Party, in pricing its products should [could] consider "Affordable price" for developing countries as a price no higher than marginal cost per unit + X% (e.g. 5%), while for least developed countries at "no profit no loss".] **(AFRO SECTION H)**

(c) Payments by Third Parties (Source: Sect. STC) **(AFRO SECTION H)**

(i) In the case that the Third Party commercializes substances, processes, products including vaccines, anti-virals, diagnostics or any other products or technologies derived from the Biological Materials for Development, developed through the use of or that contain/incorporate the Biological Materials for Development, the Third Parties shall pay a X% of the Sales of the commercialisation into the mechanism [WHO managed multilateral trust fund] established for this purpose. **(AFRO SECTION H)**

[(ii) The Third Party shall submit to the WHO within sixty (60 days) after each calendar year ending December 31st, an annual report setting forth: **(AFRO SECTION H)**

(a) the Sales of the substances, products, processes by the Third Party, its affiliates, contractors, licensees and lessees for the twelve (12) month period ending on December 31st; **(AFRO SECTION H)**

(b) the amount of the payment due; **(AFRO SECTION H)**

Payment shall be due and payable upon submission of each annual report. All payments due to the WHO shall be payable in (specified currency) for the account of (the Trust Account or other mechanism established by the WHO)] **(AFRO SECTION H)**

7. Non-assignments or Transfer of Rights (AFRO SECTION H)

The Third Party shall not assign, transfer or otherwise dispose, in whole or in part, to any other parties including entities, organisations and companies any of its rights and responsibilities under the STC unless there is prior written consent of the First Party and the WHO. **(AFRO SECTION H)**

OR

Transfer to & Use by Third Parties (IGM/4 Section G)

Old 23. Second party partners may not transfer Specimens to any entities not listed in Article 19 above without receipt of a duly completed and signed Biological Materials Request Form from the party requesting the Specimens and authorization from the First Party. **(IGM/4 Section G)**

Old 24. WHO CC's may transfer free of charge Candidate Influenza Vaccine Viruses to Third Parties or other GISN Entities upon receipt of a duly completed signed GISN Biological Materials Request Form. The WHO CC shall regularly inform the State Provider of such transfers, including the name of the Third Party Recipient and the Candidate Influenza Vaccine Viruses provided. **(IGM/4 Section G)**

Old 25. WHO CC's may transfer free of charge Seasonal influenza reference viruses to Third Parties or other GISN Entities for non commercial purposes upon receipt of a duly completed signed GISN Biological Materials Request Form. The WHO CC shall regularly inform the State Provider of such transfers, including the name of the Third Party Recipient and the Candidate Influenza Vaccine Viruses provided. **(IGM/4 Section G)**

Third Parties may only request GISN Biological Materials from WHO CCs. Only WHO CCs are authorized to provide GISN Biological Materials to Third Parties. **(IGM/4 Section G)**

1. Requests from a Third Party for GISN Biological Materials will be considered only upon receipt by a WHO CC of a duly completed and signed GISN Biological Materials Request Form from the Third Party. The Request Form includes these STCs and requires the Third Party to identify the specific GISN Biological Materials requested and state the purpose for which it intends to use each specific Material. **(IGM/4 Section G)**

2. Any and all transfers of GISN Biological Materials from WHO CCs to Third Parties shall be subject to these STCs. Any transfer of GISN Biological Materials in response to receipt of a duly completed GISN Biological Materials Request Form shall be clearly labelled as "GISN Specimens" or "GISN Candidate Influenza Vaccine Viruses" or "GISN Seasonal influenza reference viruses" and a copy of these STCs shall be included in the shipping documents. **(IGM/4 Section G)**

3. Third Party Recipients of GISN Biological Materials shall not transfer, sell, offer for sale or otherwise use the Materials for purposes other than those specified on the approved GISN Biological Materials Request Form. Any use of the GISN Biological Materials that differs from or is inconsistent with the purpose stated in the GISN Biological Materials Request Form and/or these STCs will require the agreement of [the State Provider][WHO]. **(IGM/4 Section G)**

4. Where use of GISN Biological Materials results in publication of an article by a Third Party in a scientific publication, the Third Party shall ensure that proper attribution is given to the State Provider/originating laboratory and include originating country scientists in the conception, execution of the research and the drafting of the article. Proper attribution of State Provider scientists in any medical or scientific journal publication should be done in a manner that is consistent with the guidelines for authorship and acknowledgement stipulated by the International committee of Medical Journal Editors in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. **(IGM/4 Section G)**

Ownership & Intellectual Property Rights (IGM/4 Section G)

No party (including GISN Entities and Third Parties) receiving, handling and using GISN Biological Materials shall claim ownership rights over GISN Biological Materials. **(IGM/4 Section G)**

1. Any Party (including GISN Entities and Third Parties) receiving, handling and using GISN Biological Materials seeking patent protection or other intellectual property rights in respect of such Materials, shall disclose in the patent application, the country from where the Biological Materials were collected and the GISN strain designation provided by the GISN CC. **(IGM/4 Section G)**

2. Any Party that uses GISN Biological Materials in a manner that results in, or may result in, financial gain,shall consult with WHO to identify how such Party will contribute to WHO's Coordinated International Sharing of Influenza Viruses & Benefits and shall sign a Contribution Agreement to that effect. **(IGM/4 Section G)**

WHO Determination of a Public Health Emergency of International Concern (IGM/4 Section G)

1. In the event that the WHO Director General determines the existence of a Public Health Emergency of International Concern (PHEIC) as defined in the International Health Regulations (2005), or under circumstances where the detemination of a PHEIC is imminent, these STCs may be abrogated in whole or in part. **(IGM/4 Section G)**

General Provisions

Safety: All parties shall ensure that all transfers under these STCs will at all times be in compliance with all relevant national and international laws, rules, and regulations governing the handling, safe transfer and use of infectious substances and living microorganisms. **(IGM/6 4)**

Warranty: All materials delivered pursuant to these STCs are understood to be experimental in nature and may have hazardous properties. They are provided to recipients without any representation and extends no warranties whatsoever, either express or implied, as to their quality, viability, purity, merchantability, suitability or fitness for a particular purpose or that its use will not infringe any patent, copyright, trademark, or other propriety right. **(IGM/6 4)**

Indemnity: Recipients of materials shall assume all liability for any claims, costs, damages or expenses resulting from or otherwise related to the possession and use of the materials. The MS will not be liable for any loss, claim or demand made to or arising from the use, storage or disposal of the materials. **(IGM/6 4)**

Applicable Law: The applicable law shall be _____. **(IGM/6 4)**

Dispute Settlement: Dispute settlement may be initiated by the MS or the WS in relation to their respective relationships in the context of these STCs. Any dispute arising from these STCs shall be resolved through the Oversight Mechanism to be established by the WS and agreed by the MS in a World Health Assembly. **(IGM/6 4)**

Termination

When one of the parties fails to fulfil its obligations or violates any of these STCs and the aggrieved party has given the other party notice of not less than 30 days in writing requiring that the failure or violation be remedied. If the failure or violation is not remedied within the said 30 days, the aggrieved party shall have the right to terminate these STCs. **(IGM/6 5)**

Upon termination, the WS shall immediately arrange discontinuation of any use of the materials in any manner including either derivation or development of substances, processes, products from the materials, and shall arrange the return or the destruction of any remaining materials. **(IGM/6 4)**

Termination of these STCs shall not affect the accrued rights and obligations that were due prior to the effective date of termination of these STCs. **(IGM/6 4)**

With regard to termination of these STCs, each Member State constitutes one party to the STCs. **(IGM/6 4)**

Notices

Any notices or requests to be made under these STCs shall be in writing and shall, except where it is otherwise stated, be delivered by courier, or by facsimile, or by electronic mail, to the address of the entity to be designated by each party, and shall be deemed to have been received on the date of delivery, if delivered by courier, and on the first business day following the electronic confirmation of the successful transmission of the facsimile or electronic mail, if sent by facsimile or electronic mail. **(IGM/6 6)**

Duration of Agreement

These STCs shall remain in force until otherwise determined by a World Health Assembly. **(IGM/6 7)**

OR

(1) Safety

All parties shall ensure that all transfers under the STC will at all times be in compliance with all relevant national and international laws, rules and regulations governing the handling, safe transfer and use of infectious substances and living modified organisms resulting from modern biotechnology. *(cf. para 16 Sect STC)* ***(AFRO Section E)***

(2) Warranty

All Biological Material, CIVV, Biological Material for Development delivered pursuant to this STC is understood to be experimental in nature and may have hazardous properties. They are provided to recipients without any representations and extends no warranties whatsoever, either express or implied, as to their quality, viability, purity, merchantability, suitability or fitness for a particular purpose or that its use will not infringe any patent, copyright, trademark, or other proprietary right. *(cf. para 14 Sect. STC)* ***(AFRO Section E)***

(3) Indemnity

Recipients of Biological Material, CIVV, and Biological Materials for Development shall assume all liability for any claims, costs, damages or expenses resulting from or otherwise related to the possession and use of the Biological Material, CIVV and Biological Materials for Development. The First Party will not be liable to the Second or Third Party for any loss, claim or demand made by the Second or Third Party, or made against the Second or Third Party by any other party, due to or arising from the use, storage or disposal of the Biological Material, CIVV and Biological Materials for Development. *(Source: para 15 Sect. STC)* ***(AFRO Section E)***

(4) Dispute Settlement

(a) Dispute Settlement may be initiated by any of the Parties in relation to their respective relationships in the context of the STC. ***(AFRO Section E)***

(b) All Parties agree that the First Party has the right as a "[Contributor and] Beneficiary", to initiate dispute settlement procedures in relation to the agreement between the WHO and the Third Party. ***(AFRO Section E)***

(c) The First Party as the "Beneficiary" also has the right to request all relevant information, biological material and/or samples as necessary, be made available by the Second, Third Parties and the WHO, regarding their obligations in the context of the STC. The WHO, Second Party and the Third Party shall provide any information, biological material and/or samples so requested as the case may be. ***(AFRO Section E)***

(d) Any dispute arising from this Agreement shall be resolved in the following manner: ***(AFRO Section E)***

(i) Amicable dispute settlement: The parties shall attempt in good faith to resolve the dispute by negotiation. ***(AFRO Section E)***

(ii) Mediation: If the dispute is not resolved by negotiation, the parties may choose mediation through a neutral third party mediator, to be mutually agreed. Parties may also agree to refer the dispute to the WHO Director General, who shall make every effort to settle it. ***(AFRO Section E)***

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. ***(AFRO Section E)***

Failing such agreement, the party that wishes a dispute to be referred to an arbitration tribunal shall give notice to the other party in writing specifying the person it has appointed as an arbitrator on its part. The other party shall appoint one arbitrator on its part within 60 days from receipt of such notice. The two arbitrators nominated by the parties shall appoint the third arbitrator who shall preside over the arbitration tribunal. Should the two arbitrators fail to appoint a third arbitrator, the Director General of WHO shall appoint the third arbitrator. ***(AFRO Section E)***

(iv) All parties shall facilitate the work of the Tribunal and, in particular, using all means at their disposal, shall provide it with all relevant documents, information and facilities; and enable it, when necessary to call witness or experts and receive their evidence. ***(AFRO Section E)***

(v) The decision of the arbitration tribunal shall be final and binding on the parties without appeal. ***(AFRO Section E)***

5. Termination *(AFRO Section E)*

(i) When one of the parties fails to fulfill its obligations or violates any of the Standard Terms and Conditions and the aggrieved party has given the other party notice of not less than 30 days in writing requiring that the failure or violation be remedied. If the failure or violation is not remedied within the said 30 days, the aggrieved party shall have the right to terminate this Agreement. ***(AFRO Section E)***

(ii) When an order has been made or resolution has been passed for the winding up or liquidation of the Third Party's establishment, the WHO shall terminate the Agreement***(AFRO Section E)***.

(iii) Upon termination, the Second and Third Parties shall immediately discontinue to make any use of the Biological Material, CIVV or Biological Materials for Development in any manner including either to derive or develop substances, processes, products from the Biological Material, CIVV or Biological Materials for Development and shall return or destroy any remaining Biological Material, CIVV or Biological Materials for Development. ***(AFRO Section E)***

(iv) The Second and Third Parties, at its discretion will also either destroy substances and products derived, developed through the use of, or that contains/incorporates the Biological Material, CIVV or Biological Materials for Development or remain bound by the terms of this agreement as they apply to those subject matter.

(v) Termination of the agreement shall not affect the accrued rights and obligations that were due prior to the effective date of termination of the agreement. ***(AFRO Section E)***

6. Notices

(a) Any notices or requests to made under the STC shall be in writing and shall except where it is otherwise stated be delivered by courier, or by facsimile to the address of the Second and Third Party as set out in the Implementing Letter or to the focal points of the First Party and the WHO. Notices and Requests shall be deemed to have been received on the date of delivery, if

delivered by courier, and on the first business day following the electronic confirmation of the successful transmission of the facsimile, if sent by facsimile. ***(AFRO Section E)***

A copy of any notices or requests given under the STC by the First, Second and Third Party should also be sent to the WHO. ***(AFRO Section E)***

7. Duration of Agreement

The STC shall remain in force until otherwise determined by the World Health Assembly ***(AFRO Section E)***

OR

Conditions (IGM/4 Section D)

2. Specimens are provided free of charge by a First Party (NIC or non-NIC) to the Second Party partners in fulfilment of their public health responsibilities, including those contained in the International Health Regulations (2005). In return, the Second Party partners will provide, free of charge, to the First Party, ~~C~~candidate ~~I~~influenza ~~V~~vaccine ~~V~~viruses, ~~I~~influenza ~~R~~reference ~~V~~viruses and ~~D~~diagnostic ~~R~~reagents [UK: This is acceptable but only if Definition 6 is narrowed as suggested above and in accord with Julie Hall's summary.] , sequence information, outcome of the Risk Assessment, and access to benefits [USA: These benefits are as yet undefined.] **(IGM/4 Section D)**

3. Biological ~~M~~aterials are provided to any recipients without any warranty whatsoever, either express or implied, as to their quality, viability, purity, merchantability, suitability or fitness for a particular purpose. The recipient shall ensure that the ~~B~~biological Materials will at all times be used and/or handled in compliance with all relevant and applicable national and international laws, rules and regulations governing the use of biological materials. The recipient agrees to assume full and sole responsibility for any and all claims and liabilities resulting from or otherwise related to the possession and use of the Biological Materials. **(IGM/4 Section D)**

4. Recipients of Biological Materials shall assume all responsibility for any claims, costs, damages or expenses resulting from or otherwise related to the possession and use of the Biological Materials. Recipients undertake to handle Biological Materials in a safe and proper manner, complying with all relevant national and international laws and regulations applicable to the handling of infectious substances. **(IGM/4 Section D)**

Virus Tracking System

WHO shall develop a database accessible to Member States to track movement of all viruses and seed viruses. **(IGM/5 Fundamental Elements 12)**

The WS shall establish a tracking system and database for transfer and movement of materials and their derivatives (including but not limited to throat, nasal, nasopharyngeal, and other swabs; blood or parts thereof; viral isolates and parts thereof including genetic characteristics, biological characteristics, clones, plasmids, and recombinants) on a real-time basis. **(IGM/6 9)**

OR

Whenever any of the Parties transfers Biological Material or CIVV or Biological Materials for Development in accordance with the STC, relevant information concerning the transfer must be included in the WHO tracking database. **(AFRO Section E)**

IDWG Singapore Annex 1

World Health Organization (WHO)

Global Influenza Surveillance Network (GISN)

GISN BIOLOGICAL MATERIALS REQUEST FORM

This Form must be completed, signed and sent by fax or e-mail to a WHO Collaborating Centre for Reference and Research on Influenza

* * *

Institution/Company Requesting GISN Biological Materials

Name & Address **Phone/E-mail Contact Information**

_____ _____

_____ _____

GISN Specimens ☐ **Seasonal Influenza** ☐ **Candidate Influenza** ☐

Reference Viruses ☐ **Vaccine Virus** ☐

GISN Strain Designation of Materials Requested:

_____

_____

_____

Purpose for use of GISN Specimens:

_____

_____

_____

Financial Gain anticipated **YES** ☐ **NO** ☐

from Use of Specimens?

If **YES** I undertake to consult with WHO as specified in Paragraph 37 of the World Health Organization Global Influenza Surveillance Network Standard Terms and Conditions for Transfer and Use of GISN Specimens (STCs).

By signing and submitting this Request Form I confirm that I have read and accept the STCs.

Name & Title	**Date**

APPROVED: **YES** ☐ **NO** ☐

Name & Title	**Date**

cc: State Provider, WHO/GIP

COPY OF THIS FORM MUST BE INCLUDED WITH THE SHIPPING DOCUMENTS

AFRO ANNEX 1

ANNEX 1

WORLD HEALTH ORGANIZATION (WHO)

NEW FRAMEWORK FOR VIRUS SHARING AND BENEFIT SHARING (NFVSBS)

IMPLEMENTING LETTER

This document must be duly completed and signed, with a copy sent by fax, courier or email by the First Party to the World Health Organization[1]

The purpose of this letter is to provide a record of the biological material transfer, to memorialize the agreement between the FIRST PARTY (identified below) and the SECOND PARTY (identified below) to abide by the Standard Terms & Conditions and to certify that the SECOND PARTY (identified below) has accepted and signed an unmodified copy of the Standard Terms and Conditions.

The SECOND PARTY organization's Authorized Official will sign this letter on behalf of the SECOND PARTY's organization. The Authorized Official of SECOND PARTY should sign this letter and return a signed copy by fax or email or courier to the FIRST PARTY.

The FIRST PARTY will forward the biological material to the SECOND PARTY upon receipt of the signed copy from the SECOND PARTY organization. This Implementing Letter is effective when signed by all parties. The parties executing this Implementing Letter certify that their respective organizations have accepted and signed an **unmodified copy of the Standard Terms and Conditions** and further agree to be bound by the terms and conditions, for the transfer of original specimen mentioned below. Please fill in all of the blank lines below:

[1] The Implementing Letter should be sent to:

[World Health Organization contact details]

1.	**Original Specimen (Enter description)**
2.	**Optional Transmittal fee** Amount: $ _____
3.	**First Party's Authorized Official (State providing the Original Specimen)**
a.	Name of Authorized Official:
b.	Address:
c.	Email Address:
d.	Tel No:
e.	Fax No:
4.	**Second Party's Organisation Certification**
I hereby certify that the _____ (name of Second Party's Organisation) has accepted and signed an unmodified copy of the Standard Terms and Conditions.	
a.	Name and Title:
b.	Address:
c.	Tel No:
d.	Fax No:
e.	Signature:

AFRO ANNEX 2

ANNEX 2: (CF. SECT STC)

WORLD HEALTH ORGANIZATION (WHO)

[GLOBAL INFLUENZA SURVEILLANCE NETWORK (NFVSBS)]

BIOLOGICAL MATERIALS REQUEST FORM &

IMPLEMENTING LETTER

This document must be completed and signed and sent by fax, courier or email to the World Health Organization

The purpose of this document is to provide a record of the request for Biological Materials for Development by the Third Party, and to memorialize the agreement between the THIRD PARTY REQUESTING BIOLOGICAL MATERIALS (identified below and hereinafter referred to as the "THIRD PARTY RECIPIENT") and the WORLD HEALTH ORGANIZATION to abide by the Standard Terms & Conditions and to certify that the THIRD PARTY RECIPIENT has accepted and signed an **unmodified copy of the Standard Terms and Conditions**.

The THIRD PARTY's Authorized Official will sign this letter on behalf of the THIRD PARTY. The Authorized Official of THIRD PARTY requesting Biological Materials for Development will complete and sign the Request Form and submit it by fax or email or courier to WHO for approval. On WHO approving the use and transfer, this Letter will constitute an agreement between the "THIRD PARTY RECIPIENT") and the WORLD HEALTH ORGANIZATION (identified below).

This Implementing Letter is effective when signed by all parties. Parties executing this document certify that their respective institution/company/organization have accepted and signed an unmodified copy of the Standard Terms and Conditions and further agree to be bound by the Standard Terms and Conditions. Please fill in all of the blank lines below.

A.	**Third Party Requesting Biological Materials for Development**
1.	**Details**
a.	**Name and Title (Authorised Official):**
b.	**Address:**
c.	**Tel No:**
d.	**Fax No:**

e. Signature:

2. Biological Materials for Development requested:

❒Candidate Influenza Vaccine Virus

3. Strain Designation of Materials Requested:

_____

_____

_____

4. Purpose of use:

❒Development and Production Seasonal Influenza Vaccine

❒Development and Production of Pre-pandemic or Pandemic Vaccine development and production

5. Provide further details of use:

_____

_____

_____

6. Third Party Recipient Certification:

By signing and submitting this document I hereby certify that our Company have read and agree to an unmodified copy of the Standard Terms and Conditions and agree to be bound by the terms. In consideration for receiving the Biological Material for Development, the

Company further undertakes to immediately enter into consultations with the WHO to operationalise paras on Benefit Sharing of the Standard Terms and Conditions.

_____ _____

(Signature) **(Date)**

_____ _____

(Name) **(Title)**

B. WORLD HEALTH ORGANIZATION

1. Approved

❒ YES ❒ NO

If Yes, provide Specific Details of Approved Use:

_____

_____

_____

_____ _____

(Signature) **(Date)**

_____ _____

(Name) **(Title)**

THE FOLLOWING IS EXTRACT FROM EB122/5 – PAGES 96–97

[1] IDENTIFICATION OF PARTIES

We believe that the parties should be defined in the same way as in IGM 4. There should be a strong link between the first and the second parties in order to strengthen and improve the collaboration within the GISN. **(EU comments received on 22 November 2007)**

RIGHTS AND RESPONSIBILITIES OF ALL PARTIES

[2] EU comments received on 22 November 2007:

- The WHO glossary of terms should be used as the basis for descriptions in the Standard Terms and Conditions. Rights and responsibilities should be in accordance with the IHR., based on this principle:

– Instead of *"Authority to determine access to influenza viruses"* the term *"authority to determine access to specimens"* should be used.
– Instead of *"specimens/virus"* the term *"clinical specimens and/wild type virus derived from them* should be used. The term *"within the STC"*should be added at the end of the second paragraph.

- We disagree with the third paragraph on the basis of the document on IGM 1, on prior informed consent.

- The right to deny access should rest with the oversight mechanism and not with the member states.

ORIGINATING COUNTRIES (MEMBER STATES)

[3] EU comments received on 22 November 2007:

- Title should read *"rights and obligations of member states"*.

- Instead of *"materials"* it should read *"clinical specimens or wild type viruses derived from them"*.

- Paragraph 7 should read *"Concerning the new global fund for vaccines, we would prefer to ask WHO to further explore the possibility of voluntary system for finance"*.

- Paragraph 8: has already been stated in the document on principles. This paragraph should therefore be deleted.

RIGHTS AND OBLIGATIONS OF THE WHO (WS)

[4] EUcomments received on 22 November 2007:

- Instead of *"receive of materials"* read *"candidate vaccine viruses, reference viruses and wild type viruses provided that international regulations on safety are respected"*.

- Paragraph 1, sub-paragraph 7 should be replaced by "Concerning the new global fund for vaccines, we would prefer to ask WHO to further explore the possibility of voluntary system for finance".

= = =