World Health Organization

INTERGOVERNMENTAL MEETING ON PANDEMIC INFLUENZA PREPAREDNESS: SHARING OF INFLUENZA VIRUSES AND ACCESS TO VACCINES AND OTHER BENEFITS
Agenda item 3

A/PIP/IGM/7
4 January 2008

Sharing of influenza viruses and access to vaccines and other benefits: Interdisciplinary Working Group on Pandemic Influenza Preparedness

In a note verbale, the Permanent Mission of the Republic of Kenya to the United Nations Office at Geneva and other International Organizations in Switzerland requested that a proposal from the Federal Republic of Nigeria on behalf of the Member States in the WHO African Region should be submitted to the Intergovernmental Meeting. The Director-General has the honour to transmit the proposal, attached herewith.

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 (IGM-PIP),
20–23 November 2007

A. PREAMBLE

WHEREAS

The World Health Assembly Resolution WHA ----- (hereinafter referred to as "the Resolution") was adopted by the 61st World Health Assembly on --- May 2008.

The Resolution recognised:

(a) the sovereign right of States over their biological resources (Source: WHA 60.28)
(b) the importance of collective action to mitigate public health risks (Source: WHA 60.28)
(c) the importance of timely international sharing of influenza viruses as a contribution to risk assessment and risk response, and the need for concrete, effective, operational and transparent international mechanisms for fair and equitable sharing of benefits (Source: WHA 60.28)
(d) that intellectual property rights do not and should not prevent Member States from taking measures to protect public health (Source: WHA 60.28)
(e) that developing and least developed countries have limited capacities and they often face economic, financial and administrative constraints. Therefore, fair and equitable benefits sharing of influenza vaccines as a result of timely international sharing of influenza virus needs to provide a more favorable condition to developing and least developed countries.

B. IDENTIFICATION OF PARTIES

1. The parties are:

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

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]:
(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[1];
(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[2];

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)*

d. **The World Health Organisation** (hereinafter referred to as "WHO")

C. DEFINITIONS

(1) **"Original Specimen"** means any biological material provided by the First Party to the Second Party of its choice as described in the Implementing Letter.

(2) **"Biological Material"** means Original Specimen, viruses and other matter isolated from the Original Specimen, and their Progeny. It also includes all of their genetic and other components (modified or unmodified), and parts thereof, including genes, sequences and polynucleotides as well as the polypeptides they encode. It further includes sequence data. *(Source: Indonesian Proposal).*

(3) **"Biological Materials for Development"** means Candidate Influenza Vaccine Virus, provided to Third Parties.

(4) **"Progeny"** means descendants such as by way of non-limiting example: virus from virus or cell from cell. *(cf. para 8 Sect. STC)*

(5) **"Candidate Influenza Vaccine Viruses"** (hereinafter also known as "CIVV") means prototype strain for influenza vaccine development, derived from selected viruses isolated from the Original Specimen and contains the Biological Material. *(cf. para 5 Sect. STC)*

(6) "**Research"** means non-commercial, scientific use of the Biological Material for global public health purposes as described in Terms of Reference.

[2] As of ….the H5RL are as follows:…….

D. SCOPE

1. The Standard Terms and Conditions (STC) governs the transfer and use of Influenza Biological Materials and fair and equitable benefit sharing:

(a) Where the First Party transfers Original Specimen to a Second Party of its choice under [the New Framework] and all parties have duly completed and signed the Implementing Letter in Annex 1; or

(b) Where a Second Party transfers the Biological Material to another Second Party under [the New Framework]; or

(c) Where a Third Party makes a request to WHO for Biological Materials for Development under [the New Framework], and the WHO has approved the request with the written consent of the First Party and all the relevant parties have duly completed and signed the Request Form/Implementing Letter in Annex 2.

2. The terms and conditions contained in this STC are binding on all parties involved in relation to (a), (b) and (c).

E. GENERAL PROVISIONS

(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.[1] *(cf. para 16 Sect STC)*

(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)*

(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)*

(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.

(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.

(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.

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

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

(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.

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 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.

(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.

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

6. Termination

(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.

(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.

(ii) 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.

(iii) 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.

(iv) 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.

7. 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.

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.

8. Duration of Agreement

The STC shall remain in force until otherwise determined by the World Health Assembly

10. Traceability

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.

F. RIGHTS AND RESPONSIBILITIES OF THE FIRST PARTY

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.

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 .

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.

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.

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.

G. RIGHTS AND RESPONSIBILITIES OF THE SECOND PARTY

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)*

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

(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.

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

(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 .

(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.

(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)*

(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)*

2. Reporting & Access to Research Output and Results by WHO and the First Party

(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)*

(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.

(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.

3. Sequence Data

(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.

4. Intellectual Property Rights

(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)*

(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.

5. Publications, Empowerment & Capacity Building

(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.

(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 WHA 60.28)*

(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.

(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.

6. Non-Assignment or Transfer of Rights

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.

H. RIGHTS AND RESPONSIBILITIES OF THE THIRD PARTIES

1. Request for Biological Materials

(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)*

(b) The Third Party shall have the right to receive/access Biological Materials for Development from the Second Party which are authorised 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)*

2. Permitted Use

(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)*

(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.

3. Intellectual Property Rights

(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)*

(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.

4. Service Providers

(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.

5. Publication, Empowerment & Capacity Building

(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)*

(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.

(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.

6. Benefit Sharing

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

(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.

(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]

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

(i) During the pre-pandemic the Third Party shall prioritise 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.

(ii) In the pandemic period, the Third Party shall prioritise 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.

[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".]

(c) Payments by Third Parties (Source: Sect. STC)

(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.

[(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:

(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;

(b) the amount of the payment due;

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)]

7. Non-assignments or Transfer of Rights

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.

I. RESPONSIBILITIES OF THE WHO

(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.

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

(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.

(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.

(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.

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 Organisation[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 Organisation 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:

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 Organisation

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 ORGANISATION 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 ORGANISATION (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

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 ORGANISATION

1. Approved

❒ YES ❒ NO

If Yes, provide Specific Details of Approved Use:

_____

_____

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(Signature) **(Date)**

_____ _____

(Name) **(Title)**

ANNEX 3 (REVISION TO THE EXISTING TOR)

All activities by the WHO Collaborating Centres for Reference and Research on Influenza under this Terms of Reference will be subject to the Standard Terms and Conditions.

a. Provide:

• Recommendations to WHO on suitable influenza vaccine viruses for use in seasonal, pre-pandemic and pandemic influenza vaccine development and production;

• Regular and timely surveillance data to WHO, particularly from local and neighbouring geographical regions;

• Advice to the WHO Global Influenza Surveillance Network (GISN)ii National Influenza Centres and other national laboratories designated by the State on laboratory methods for the diagnosis of influenza, the adoption of new diagnostic approaches, the improvement of laboratory practices and on other operational needs;

• Regular and timely reports of virus characterization to WHO and the country contributing the virus and GISN members

• Expertise, continuous training and laboratory support to WHO Member States in particular developing countries facing influenza outbreaks to conduct influenza outbreak investigation, risk assessment and response activities, including developing candidate influenza vaccine virus.

and response, especially those with pandemic potential; and

• Expertise to assist WHO on the improvement of global surveillance of influenza viruses causing or with the potential to cause human infections, including the development and revision of relevant policies, recommendations and guidelines.

b. Conduct:

• Isolation and analysis in both embryonated eggs and cell culture of influenza viruses causing or with the potential to cause human infections;

• Complete antigenic and genetic analysis of influenza viruses causing or with the potential to cause

human infections, making the information available to WHO and the originating country in a timely manner;

• Antiviral susceptibility testing and analysis of circulating influenza strains and provide a minimum of

two reports each year to WHO and the originating country on the findings;

• Active communication and collaboration with other laboratories, especially with the WHO recognized

National Influenza Centresiii to ensure that high quality clinical specimens and/or virus isolates are

received and information is exchanged;

c. Develop, produce and distribute:

• Antisera against representative influenza viruses causing or with the potential to cause human

infections to WHO laboratories involved in influenza vaccine virus selection, development and other

WHO activities; and

• Laboratory diagnostic reagents for circulating influenza viruses to GISN members.

d. Participate in:

• Bi-annual WHO influenza vaccine composition consultations; and

• WHO process to select, develop and distribute candidate influenza vaccine viruses for influenza

pandemic preparedness and response.

ANNEX 4 (REVISION TO EXISTING TOR)

TERMS OF REFERENCE FOR WHO H5 REFERENCE LABORATORIES

In 2004, the WHO H5 Reference Laboratory Network was established, as an *ad hoc* component of the WHO Global Influenza Surveillance Network (GISN)1, in response to the public health needs arising from avian influenza A(H5N1) infection in humans and influenza pandemic preparedness. The laboratories involved to date2 include the four WHO Collaborating Centres for Reference and Research on Influenza, the WHO Collaborating Centre for Studies on the Ecology of Influenza in Animals and other laboratories with internationally recognized expertise in avian influenza.

The addition of new laboratories to the Network is based on an overall assessment of global public health needs, the ability of candidate laboratories to fulfil the Terms of Reference listed below, and, in particular, the added value that inclusion of candidate laboratories would bring to the Network.

Membership in the WHO H5 Reference Laboratory Network is *ad hoc* and will be reviewed periodically to ensure the Network's optimum effectiveness in meeting emerging public health risks.

A. Provide

1. accurate laboratory diagnosis of influenza infection in humans to assist in rapid outbreak response, especially those suspected of being associated with avian influenza A (H5) viruses;

2. Expertise and laboratory support in response to A (H5) avian influenza outbreaks

3. immediately report to WHO and the originating laboratory the results of laboratory diagnostic tests, especially the detection of A (H5) viruses and any other important findings;

4. feedback to WHO on the use of WHO recommended diagnostic protocols and primers to assist WHO in the update of laboratory diagnostic recommendations.

B. Actively seek approval from the Ministry of Health of the originating laboratory for sharing the A (H5) clinical specimens and/or viruses with any other entity.

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