

BANGLADESH PABS TEXT PROPOSAL

OUTLINE & KEY ELEMENTS FOR ANNEX ON WHO PATHOGEN ACCESS AND BENEFIT SHARING SYSTEM (PABS SYSTEM)

This **interim submission** is intended to advance the PABS Annex negotiations at IGWG. This submission, which contains some suggested elements and texts to be addressed by the Annex, is without prejudice to any **further/revised** elements and textual proposals and suggestions to be put forward jointly or individually as the discussion progresses.

A. OBJECTIVE

The objective of this Annex is to improve pandemic preparedness and response and strengthen the protection against the PHEIC and/or the Pandemic by establishing a safe, transparent and accountable multilateral WHO Pathogen Access and Benefit Sharing System pursuant to Article 12 of the Pandemic Agreement for, on an equal footing,:

- (i) The sharing of PABS Materials and Sequence Information; and,
- (ii) The access to vaccines, therapeutics and diagnostics (VTDs) and sharing of other benefits.

B. SCOPE

1. The Annex applies to the rapid and timely sharing of “materials and sequence information on pathogens with pandemic potential” (hereinafter “PABS Materials and Sequence Information”) and, on an equal footing, the rapid, timely, fair and equitable sharing of benefits arising from the sharing and/or utilization of PABS Materials and Sequence Information.
2. For the purpose of the Annex “pathogen with pandemic potential” means [placeholder]
3. The PABS System shall operate complementarily to the PIP Framework. In recognition of their complementary nature, the operation of the PABS System shall extend to H5N1 and other influenza viruses with human pandemic potential, where cooperation under the PIP Framework is absent or insufficient.

[JUSTIFICATION: The two instruments have difference in their legal status. The difference in legal status doesn't prevent the PABS System and the PIP Framework from being complementary, but it does create a hierarchy of enforceability. The proposed text above has duly taken into consideration this hierarchy of enforceability. The PIP Framework is not legally binding for the WHO Member states. The SMTA 2 under the PIP Framework between the WHO and the recipient entities is legally binding, which does not entail any legal obligations for the states. What if a state does not comply with the commitments made under the PIP Framework? There should be provision for bringing states under obligations to make sure that they do cooperate during a PHEIC and/or Pandemic caused by influenza viruses with pandemic

potential primarily and voluntarily through the PIP Framework and, if not, mandatorily through the PABS System.]

4. All elements of the PABS System shall come into operation simultaneously.
5. The PABS System shall operate irrespective of origin or source of the PHEIC and/or Pandemic for realization of the purpose of the Pandemic Agreement.

[JUSTIFICATION: Unlike the IHR, 2005, the Pandemic Agreement may suffer from a legal loophole during a public health emergency, since it has not explicitly referred to its source neutrality in the texts. Source neutrality means that the treaty obligations under international law apply regardless of the origin of a public health threat—whether it arises from natural, accidental release, or deliberate use of pathogens (e.g., bioterrorism or bioweapon as a means of warfare). **The Pandemic Agreement is implicitly source-neutral**, as it focuses on pandemic prevention and response mechanisms, without distinguishing among the origins (i.e., by remaining silent on them). **The PABS Annex should not follow the same approach of implicit source neutrality.** Since, in the Pandemic Agreement, this is an absence rather than an explicit affirmation (of source neutrality), it remains an issue subject to interpretation rather than a formally stated principle. In legal interpretation, it is highly likely to suffer from the 'scope limitation by silence'. Since article 4 of the Pandemic Agreement has addressed only natural causes, the general rules of treaty interpretation (1969 Vienna Convention on the Law of Treaties article 31) may favour narrow interpretation (i.e., applicable to natural outbreaks only) of the scope of the Pandemic Agreement and the PABS System during a public health emergency.

Given the formidable challenge of source attribution, and its vulnerability to geo-political manoeuvring (e.g., even a naturally occurring Pandemic may be labelled as one originating from lab leak or deliberate use of pathogens), the Pandemic Agreement and the PABS System may struggle to deliver in such scenario (further details can be shared in support of this claim). Arguments may be made to address the outbreak under the Biological and Toxin Weapons Convention (BTWC) and/or UN Secretary General's Mechanism (UNSGM). Countries may argue for making pandemic response conditional to attribution, accountability, and enforcement, which BTWC cannot do because of its lack of verification, and compliance mechanism. This is a grave danger facing public health emergency response, which the drafters of **International Health Regulations (IHR)** duly sensed. Accordingly, they carefully avoided implicit source neutrality. **Instead, they adopted explicit source neutrality (IHR article 7) by clearly mentioning 'irrespective of origin or source'.** To our understanding, explicit source neutrality approach is, undoubtedly, the potent way to safeguard any PHEIC and/or Pandemic response from geo-political manoeuvring, as numerously manifested through IHR's real-time efficacy. We think that the PABS System should adopt similar approach to avoid any unnecessary debate over its scope of application. **Including this sub-para 5 into the Annex can also make sure that the Pandemic Agreement has clear mandate over any PHEIC and/or Pandemic irrespective of origin or source** (ref. Vienna Convention on the Law of Treaties article 31 (3) (b)). The destiny of humanity should not be left to the whims of geopolitics.]

C. DEFINITIONS FOR THE PURPOSE OF THE ANNEX

1. PABS Materials: (i) isolated wild-type pathogens assessed to have pandemic potential, and parts thereof; (ii) any modified forms of such pathogens; and (iii) any other materials derived from, generated or prepared using the materials described in (i) and (ii).

2. PABS Sequence Information: any data or information generated from PABS Materials through the application of sequencing technologies
3. Authorized national laboratories: laboratories authorized and designated by a Party to provide PABS Materials and/or PABS Sequence Information to the PABS System and recognized as part of the WHO Coordinated Laboratory Network.
4. Clinical Specimens: materials taken from humans including specimens collected from the respiratory tract (for example, swabs and aspirated fluid), and also blood, serum, plasma, faeces, and tissues.
5. Originating laboratory: a national authorised laboratory that sent the initial clinical specimens and/or the isolated pathogen with pandemic potential
6. Participating Manufacturer: public and/or private entities that develop and/or manufacture vaccines, therapeutics and diagnostics for pathogens with pandemic potential including, but not limited to, academic institutions, government owned or government subsidized entities, nonprofit organizations or commercial entities.
7. WHO Coordinated Laboratory Network an international network of authorized national laboratories coordinated by WHO and governed by the PABS System under the supervision of COP. To be a part of the WHO Coordinated Laboratory Network, an authorized national laboratory meets the criteria for designation and agree to comply with terms and conditions as set out in the Standard Contract 1, the applicable Terms of Reference, and any other requirements of the PABS system.
8. [placeholder: affordable prices]

(the above list below is non-exhaustive and may be expanded)

D. FRAMEWORK OF THE PABS SYSTEM

1. The PABS System & rapid and timely access to PABS Materials and Sequence Information

1.1 PABS Materials & Traceability Measures

1. 1.1 WHO Coordinated Laboratory Network (WCLN)

- a. WCLN coordinated by WHO under the oversight of COP, shall be established. The network shall link authorised national laboratories that meet the criteria for participating in the WCLN and agree to accept the Terms of Reference (ToR), the legally binding terms and conditions applicable to the sharing/utilization of PABS Materials and PABS Sequence Information, as well as other requirements of the PABS System.

- b. When a Party has access to a pathogen with pandemic potential identified from within a territory under its jurisdiction, it shall, taking into account national risk assessment and applicable biosafety, biosecurity and data protection standards, notify the PABS Tracking Mechanism (PABS TM) established as per para 4.1 (2) of this Annex through authorized national laboratories and obtain a PABS electronic label prior to providing the materials to one or more laboratories, of its choice, participating in WCLN.
- c. National laboratories shall make, as feasible, efforts to ensure that PABS biological materials that they provide to WCLN contain viable material and are accompanied by information as agreed in the PABS Tracking Mechanism (PABS TM) and other clinical and epidemiological information needed for risk assessment.
- d. WHO shall be responsible for facilitating the funds required to cover the costs related to shipment of PABS Materials to and within the WHO Coordinated Laboratory Network, by developing country Parties.
- e. The Parties may also provide PABS biological materials directly to any other party or body on a bilateral basis provided that the same materials are provided on a priority basis to WCLN under this Annex.

[JUSTIFICATION: States Parties to the Nagoya Protocol can share the biological materials with other parties based on bilateral contracts.]

1.1.2 Standard Legally Binding Contracts Applicable to the Sharing of PABS Materials and PABS Sequence Information

- a. All transfers of PABS Material by an authorised national laboratory to a laboratory that is part of WCLN and further transfers within WCLN are subject to Standard Contract 1.
- b. By providing PABS Materials to laboratories designated as part of the WHO Coordinated Laboratory Network, the provider Party provides their consent for the onward transfer to and use of PABS Materials by Recipient Entities outside the WCLN that have signed Standard Contract 2 with WHO. Recipients agree not to transfer or share PABS materials to entities outside WCLN that have not signed Standard Contract 2.
- c. Both Standard Contract 1 and 2 shall contain terms and conditions applicable to the storage, sharing, and use of sequence Information generated by recipients from PABS Materials.

1.2 PABS Sequence Information & Traceability Measures

1.2.1 WHO Coordinated Database Network (WCDN)

- a. Sharing of any PABS sequence information shall be through a WHO PABS Sequence Database that is transparent and accountable to Parties and implements requirements set out in sub-paragraph (f) and COP decisions. WHO may host such a database or may, following a COP decision, organise an existing database to host the WHO PABS Sequence Database.

- b. Other databases may access and share PABS sequence information, subject to the database entering into a legally binding contract with WHO, agreeing to comply with terms and conditions set out in sub-paragraph (f) (hereinafter referred to as “Participating Databases”).
- c. WHO PABS sequence database, along with participating databases constitute WCDN.
- d. The Parties shall notify the PABS Tracking Mechanism (PABS TM) and obtain a PABS electronic label prior to providing the Sequence Information to WCDN.
- e. In the event that the publication of Sequence Information has been considered sensitive by the Party providing the PABS Biological Materials and Sequence Information in some instances, the WHO Director General shall consult with the PABS Advisory Group established as per para 5.2 of the Annex on the best process for further discussion and resolution of issues relating to the handling of Sequence Information under this annex.
- f. WHO PABS Sequence Database and other Participating Databases hosting PABS Sequence Information to comply with terms and conditions including:
 - (i) require registration and acceptance of Data Access Agreement (Standard Contract 3) from all users of database intending to access PABS Sequence Information;
 - (ii) provide access to PABS Sequence Information to all registered users, whose identity is verified, without any fee charged and without any form of discrimination.
 - (iii) attach persistent unique labels to sequence files or datasets in a manner identifying originating country of the PABS materials from which sequence information is generated
 - (iv) make available facilities for registered users to link their scientific or other publications, provide information of R&D progress and R&D outcomes that use/refer to PABS Sequence Information;
 - (v) provide information related to usage of databases, including a list of registered users as well as other particulars, to WHO periodically and/or upon request.
 - (vi) agree to comply with all requirements of PABS system and act in accordance with WHO/COP decisions in this regard.
 - (vii) In the event, the participating database is generating revenue from the sharing/utilization of PABS Sequence Information, the participating database agrees to contribute towards monetary benefit-sharing;

1.2.2 Standard Legally Binding Contract Applicable to the Sharing of PABS Sequence Information

- a. Parties to take measures to ensure that PABS sequence information is shared through the WHO PABS Sequence Database and consistently with its requirements.
- b. Laboratories within WCLN to share all PABS Sequence Information through the WHO PABS Sequence Database.
- c. Submission of PABS Sequence Information to be based on the format as decided by the COP, and such format shall include requiring the submitter to provide information on the country of the originating laboratory

2. The Parties agree that the users shall not claim any intellectual property or other rights that limit the access or use of the biological materials shared, their genetic parts or components, including genetic sequence data or parts thereof.

3. Fair and Equitable Benefit-Sharing from Recipients of PABS Materials and Sequence Information (to be reflected in Standard Contracts 2 and 3)

3.1 Annual Monetary Contributions (applicable to all recipients accessing PABS Materials and/or PABS Sequence Information)

- When revenue is generated from the sharing/utilization of PABS Materials and/or PABS Sequence Information, to annually contribute x% of total annual revenue for each product or service developed and commercialised using the PABS System. Annual revenue includes all financial benefits such as income from sales and royalties.

3.2 Non-monetary Benefit Sharing

a. Participating manufacturer:

(i) in the event of a pandemic emergency, to make available make available to the WHO rapid access targeting 20% of their real time production of safe, quality and effective vaccines, therapeutics, and diagnostics for the pathogen causing the pandemic emergency, provided that a minimum threshold of 10% of their real time production is made available to the WHO as a donation, and the remaining percentage, with flexibility based on the nature and capacity of each participating manufacturer, is reserved at affordable prices to the WHO, in accordance with paragraph 6 of Article 12.

(ii) to provide to WHO on request, at not-for-profit prices and on a priority basis, the vaccines, therapeutics and diagnostics, for stockpiling and/or to supply affected developing countries, to prevent, prepare for and respond to a PHEIC. **The set-asides to be determined in IGWG**

(iii) in the event of a PHEIC and/or a pandemic emergency, to grant WHO non-exclusive licenses that can be sublicensed to manufacturers in developing countries, especially to those that provided PABS Materials and PABS Sequence Information, for the development and/or production of pandemic-related products needed in developing countries, to expand supply rapidly, ensuring prompt equitable access in developing countries. Such a license to include provision of the full regulatory dossier, technical know-how, and any necessary materials (e.g. cell-lines etc.).

b. Recipients accessing PABS Materials and/or PABS Sequence Information for strictly for Non-Commercial uses (not intended to generate revenue)

1. The Parties agree that entities that use PABS Materials and Sequence Information for non-commercial purposes shall:

- (a) include scientists from originating laboratories, institutions or countries in research collaboration and scientific publications;
- (b) acknowledge the providers of the PABS Materials and Sequence Information in relevant presentations or publications;
- (c) contribute to public dissemination and transparency of publication or any other outputs by making the results available through the PABS TM with an additional obligation of reporting through the WHO PABS Sequence Database such that it shall be linked to the sequence information accessed;
- (d) actively engage in scientific or academic collaborations, training and capacity building activities, and consider voluntary monetary contributions to support the PABS System;

2. In the event that a non-commercial user becomes a commercial user or a relevant manufacturer or entities for the purposes of commercial use and/or utilization under this section, that user shall be subject to terms and conditions applicable to commercial users and relevant manufacturers and entities.

c. Other Recipients [if any]

3.3 Other Non-monetary Benefit Sharing

[Note: These following paragraphs, which detail responsibilities of both the Parties and the Entities can be either voluntary or mandatory or combined depending on the negotiations at IGWG. Accordingly, the texts of the articles will develop.]

a. Capacity building & technical assistance

(i) The Parties shall cooperate in the capacity-building, capacity development and strengthening of human resources and institutional capacities to effectively implement this PABS System in developing country Parties including through existing global, regional, subregional and national institutions and organizations.

(ii) The need of developing country Parties shall be taken fully into account for capacity-building and development to implement this Annex.

(iii) The WHO shall play a pioneering role in the capacity-building, capacity development and strengthening of human resources and institutional capacities to effectively implement this PABS system in developing country Parties particularly to make sure that the national laboratories can meet the criteria to participate in the WCLN.

(iv) Upon request, the Parties with advanced laboratory capacities shall work with WHO and other Parties, particularly developing countries, to develop national laboratory and pathogen surveillance capacity, including:

- (a) to conduct early detection, isolation and characterization of pathogens with pandemic potential;
- (b) to participate in pandemic risk assessment and response;
- (c) to develop research capacity related to pathogens with pandemic potential;

(v) Upon request, the Parties with advanced regulatory capacity shall work with WHO, particularly in developing countries, to strengthen the capacity of regulatory authorities to carry out the necessary measures for the rapid approval of safe and effective VTDs, including products developed from the use of the PABS Materials and Sequence Information.

(vi) The Parties shall make publicly available information on the notification of health regulatory approval of VTDs for pathogens with pandemic potential including those developed from the use of the PABS Materials and Sequence Information.

(vii) [Capacity building obligations of the actors other than the Parties may be included in the standard contract texts.]

b. Research and development cooperation

(i) The Parties shall cooperate in scientific research and development involving the PABS Materials and Sequence Information sourced from developing countries.

(ii) The Parties shall ensure that the benefits arising from such research are shared in a fair and equitable manner, including but not limited to: sharing research results, joint authorship in publications, co-ownership of intellectual property rights, royalties from commercial products and access to scientific knowledge, data and relevant technologies.

(iii) Acknowledging that capacity building in scientific and technological fields shall be a core component of such cooperation with the aim of empowering developing countries to participate fully in the research process and the subsequent utilization of its results, the Parties with advanced research and development capabilities shall encourage their commercial and non-commercial users of the PABS Materials and Sequence Information to include originating laboratories, institutions or countries in research and development collaboration.

(iv) [R&D obligations of the actors other than the Parties may be included in the standard contract texts.]

c. Technology transfer

(i) The WHO Director General shall work closely with the Parties and VTD manufacturers to increase VTD supply, including its strategies to build new production facilities particularly in developing countries and through transfer of technology, skills and know-how.

(ii) The Parties shall encourage VTD manufacturers to make specific efforts to transfer these technologies to other countries, particularly developing countries, as appropriate.

(iii) Technology transfer shall be conducted in a manner consistent with applicable national laws and international laws and obligations facilitated progressively over time, on mutually agreed terms, and be suitable to the capacity of recipient Parties, to empower developing countries to study and manufacture VTDs.

(iv) [Technology transfer obligations of the actors other than the Parties may be included in the standard contract texts.]

d. [Non-exhaustive list of other non-monetary benefits can be mentioned following the Nagoya Protocol]

3.4. Modalities of distribution of the benefits

[Public health risk and need at the Agreement's Article 12 (6) (b) need to be clarified. The PABS Annex should determine clear criteria e.g., proximity to outbreaks, population density in affected or at-risk areas etc. for the distribution of benefits.]

4. Other key provisions administering the PABS System

4.1 Transparency, Traceability & Reporting Mechanism

1. Access to PABS Materials and Sequence Information shall be subject to the prior informed consent of the Party providing such resources and mutually agreed terms between providers and users of such resources.

2. WHO to establish a PABS Tracking Mechanism (PABS TM) to record all transfers of PABS Materials

3. WHO to make publicly available:

- a. the list of registered recipients of PABS Sequence Information;
- b. the list of WCLN labs
- c. monetary contributions received from each recipient and their utilization;
- d. standard contracts 2 & 3 concluded with each recipient.

4.2 Consistency with applicable practices, rules and laws related to risk assessment, biosafety, biosecurity, export control of pathogens, and data protections

1. The Parties shall utilize the PABS system in their pandemic surveillance, risk assessment and response, early warning information and services to all the Parties. The use of PABS Materials under the system shall follow applicable practices, rules and laws related to risk assessment and response.

2. The sharing of the PABS materials shall be subject to appropriate biosafety guidelines and regulations and employ laboratory protection best practices.

3. Diversion of the PABS Materials and Sequence Information and their derivatives for military purpose is prohibited and shall be in violation of the applicable international norms and law.

[JUSTIFICATION: Given the sensitivity and importance of the issue, it should be mentioned in the general text of the Annex in addition to the Standard Contracts. The benefit of placing it here is that the obligations will cover all including the Parties, WCLN laboratories, WCDN databases and other users of PABS Materials and Sequence Information.]

4. The Parties shall harmonise their national legislation and practices on export control with the requirements of the PABS system.

5. When the PABS Materials and Sequence Information are accessed, the individuals or entities accessing those make sure that sensitive information is protected and only shared appropriately. The PABS system demands due diligence from users, who must seek, keep, and transfer relevant information, and compliance measures to prevent unauthorised access or use.

4.3 Relationship with other international frameworks, regulations and agreements

1. The PABS System shall consistently operate with the objectives of the Nagoya Protocol of the Convention on Biological Diversity.

2. The PABS System shall operate complementarily to the PIP Framework. WHO shall continue to apply the PIP Framework to the sharing of H5N1 and other influenza viruses of human pandemic potential, including benefit sharing. In recognition of their complementary nature, the operation of the PABS System shall extend to H5N1 and other influenza viruses with human pandemic potential, where cooperation under the PIP Framework is absent or insufficient.

[Note: Part of it is also mentioned in SCOPE of the Annex.]

3. **[The relationship of the PABS system with the International Health Regulations needs to be mentioned.]**

4. The PABS system shall operate without prejudice to and complement the relevant provisions of the 1972 Biological and Toxin Weapons Convention (BTWC).

[JUSTIFICATION: Discussions under the Article X of the BTWC are ongoing to facilitate cooperation and assistance through mechanisms in the fields of biological science and technology. The Convention has also envisaged international response to use of deliberate use of pathogens as mentioned in Article VII.]

4.4 Alignment of national legislation or regulatory requirements on access and benefit sharing and dispute resolution

1. The Parties shall take all steps to facilitate the rapid and timely manufacture and export of vaccines, therapeutics and diagnostics, and to operationalise other benefit-sharing obligations that recipients have committed to provide to prevent, prepare for and to respond to a PHEIC and/or a pandemic emergency for pathogens covered by the PABS system.

2. Each Party, in respect of such a user operating within its jurisdiction, shall take the necessary legislative, administrative or policy measures to ensure non-state actors with all components of the PABS System comply with the terms and conditions of the PABS System.

3. The Parties shall cooperate and take appropriate measures, such as conditions in public procurements or on public financing of research and development, pre-purchase agreements, or regulatory procedures, to ensure that users of the PABS System comply with their respective benefit sharing commitments, including that relevant manufacturers and entities conclude the PABS contracts as early as possible.

4. The Parties shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 and 2 above.

5. The Parties shall, as far as practicable and as appropriate, cooperate in cases of alleged violation of domestic access and benefit sharing legislation or regulatory requirements referred to in paragraph 1 and 2 above.

6. The Parties may bring to the attention of the WHO Director General allegations of non-compliance by WCLN laboratories, WCDN databases and any other recipients with their respective terms of reference or the Standard Contracts for further necessary actions elaborated at para 5.4, 5.5. and 5.6.

5. Governance, Monitoring and Review of the PABS System

5.1 PABS system to be coordinated and administered by the WHO, under authority of the COP. WHO to take all measures necessary to ensure a fair, transparent, equitable, effective, efficient and accountable implementation of the PABS System.

5.2 An independent, free of conflict of interests, oversight “PABS Advisory Group” to be established to monitor and to provide guidance to WHO on the functioning of the PABS system in accordance with the terms of reference for the Advisory Group. The PABS Advisory Group to present an annual report to the COP on its evaluation of the implementation of the PABS system, with its recommendations for COP’s approval.

5.3 The Director-General, in consultation with Member States, to ensure that the PABS Advisory Group is based on fair and equitable representation of the WHO regions, taking into account the importance of representation from developing countries. The PABS Advisory Group shall comprise xx members drawn from each WHO Region, with a skill mix of internationally recognized policy makers, public health experts and technical experts.

5.4 In the event of any alleged breaches of the terms of reference or the Standard Contract by a WCLN laboratory, the Director-General shall review the circumstances and discuss with the PABS Advisory Group any appropriate action in response to those breaches. Where there has

been a serious breach, the Director-General may consider suspending or revoking the WHO designation of the relevant laboratory.

5.5 In the event of any alleged breaches of the terms of reference or the Standard Contract by WHO PABS Sequence Database or participating databases, the Director-General shall review the circumstances and discuss with the PABS Advisory Group any appropriate action in response to those breaches. Where there has been a serious breach, the Director-General may consider suspending or revoking the WHO designation of the relevant database.

5.6 In the event of any alleged breaches of the Standard Contract by receiving entities (outside the WCLN laboratory, WHO PABS Sequence Database, and participating database), the Director-General shall review the circumstances and discuss with the PABS Advisory Group any appropriate action in response to those breaches. Where there has been a serious breach, the Director-General may consider suspending or revoking the access of such receiving entities.

5.7 Monitoring of the PABS System

[Note: There should be provision on monitoring on the implementation of the PABS System. The WHO Director-General may be tasked with reporting to the COP. PIP Framework monitoring provision can be consulted.]

5.8 Review of the PABS System

[Note: There should be provision of review by COP of the PABS System to check if the system is functioning and needs further improvement.]

E. STANDARD LEGALLY BINDING CONTRACTS

STANDARD CONTRACT 1:

TERMS AND CONDITIONS APPLICABLE TO NATIONAL AUTHORISED LABORATORIES AND WCLN LABORATORIES

Legally binding contract between the Provider (national authorised laboratory sending PABS Materials and Sequence Information) and Recipient (WCLN laboratory receiving PABS Materials and Sequence Information), to be concluded when becoming a member of WCLN. Terms and conditions to be included in the standard contract include:

1. The recipient agrees to comply with its ToR and to use the PABS Material and clinical specimen solely for public health purposes as set out in the Terms of Reference, for the prevention, preparedness and response to a pandemic, and not-for-profit.
2. All transfers of PABS Materials to be recorded in the PABS Materials Tracking Mechanism.
3. Onward transfer and use of the PABS Materials to all WCLN laboratories to be on the same terms and conditions applicable to WCLN; and to entities outside the WCLN subject to the Entity concluding Standard Contract 2 with the WHO.

4. Recipient to actively seek participation of scientists from originating laboratories, especially those from developing countries, in scientific or R&D projects associated with research on PABS Material and Sequence Information from their countries, as well as actively engage them in preparation of manuscripts for presentation, publication or any other outcomes;
5. Recipient to appropriately acknowledge in presentations and publications the contributions of collaborators, including originating laboratories/countries providing the PABS Material and Sequence Information.
6. Intellectual property shall not be sought or asserted over any PABS Materials and Sequence Information, or parts thereof, in any form, including any modified form or for any use.
7. The recipient to regularly and/or on request, share all analyses and outcomes from the sharing/utilization of PABS Materials and PABS Sequence Information with the Provider.
8. Sharing of PABS sequence information to be through the WHO PABS Sequence Database and agree to comply with the terms and conditions as applicable to the users of PABS Sequence Information.
9. Agrees to comply with COP decisions with respect to the PABS system
10. Criteria for an authorized national laboratory to ensure biosafety and biosecurity.

STANDARD CONTRACT 2:

TERMS AND CONDITIONS APPLICABLE BETWEEN WHO AND ENTITIES OUTSIDE OF WCLN

Legally binding contract between: WHO and the Recipient Entity (outside of the WCLN laboratory receiving PABS Materials and PABS Sequence Information). The recipient entity can access PABS Materials and PABS Sequence Information from WCLN, subject to the conclusion of a legally binding contract with WHO. Terms and conditions of the standard contract include:

1. using the PABS Materials and PABS Sequence Information solely and strictly for research and development in connection with pathogens with pandemic potential within the scope of the PABS system for the prevention, preparedness and response to a pandemic.
2. not be used in any activity that may lead to the development, or production of biological agents, toxins, weapons, equipment, or means of delivery specified in Biological Weapons Convention;
3. to keep WHO informed of all uses of PABS Materials and PABS Sequence Information, as well as any changes to their intended use. Any use of PABS Materials and Sequence Information outside the scope of the PABS System must obtain prior informed consent from the originating country.
4. transferring the PABS Materials only if the prospective recipient has concluded the required contract with WHO. Any such transfer shall be reported to the WHO through the PABS Tracking Mechanism.
5. sequence information generated by the Recipient from the PABS Materials, sharing/transfer through WHO PABS Sequence Database and recipient to comply with terms of data access agreement (standard contract 3)

6. not to seek or assert intellectual property over any PABS Materials and PABS Sequence Information, or parts thereof, in any form, including any modified form or for any use.
7. to comply with monetary and non-monetary benefit-sharing obligations
8. Agrees to comply with COP decisions with respect to the PABS system

STANDARD CONTRACT 3: DATA ACCESS AGREEMENT/ TERMS AND CONDITIONS APPLICABLE TO ANY PERSON/ENTITY ACCESSING PABS SEQUENCE INFORMATION FROM WHO PABS SEQUENCE DATABASE/PARTICIPATING DATABASES

Legally binding contract for parties - the Database, WHO and person/entity seeking access to PABS Sequence Information. Access to PABS Sequence Information is subject to registration and acceptance of data access agreement with terms that include:

1. use solely and strictly for research and development in connection with pathogens with pandemic potential within the scope of the PABS system for the prevention, preparedness and response to a pandemic;
2. not be used in any activity that may lead to the development, or production of biological agents, toxins, weapons, equipment, or means of delivery specified in Biological Weapons Convention;
3. transfer or share sequence information only if the prospective recipient is also a registered user either of the WHO PABS Sequence Database or a Participating Database;
4. acknowledge the contributions of the persons and institutions who submitted the sequence information as well as the originating laboratories that first collected the clinical specimen and isolated the pathogen with pandemic potential;
5. actively seek the participation of scientists from originating laboratories/countries of PABS Materials and clinical specimens from which the PABS Sequence Information was generated, especially those from developing countries, in scientific or R&D projects associated with the PABS Sequence Information, and to actively engage them in the development and implementation of the projects;
6. not seek or assert intellectual property over PABS Sequence Information or parts thereof, in any form, including any modified forms or for any use;
7. Agrees to comply with the monetary and non-monetary benefit-sharing obligations.
8. Agrees to comply with COP decisions with respect to the PABS system

(Standard contract 3 may potentially be in a form of a click-wrap agreement)