WHO BioHub System

The following package of two documents is to be used for the WHO BioHub System Pilot Testing Phase (Stream 1) to demonstrate proof of concept of the project and to inform potential further discussions of the WHO BioHub initiative. It aims at enabling voluntary sharing of Biological Materials with Epidemic or Pandemic Potential (BMEPP) – specifically, during this pilot testing, solely for SARS-CoV-2 – into and from a WHO BioHub Facility for non-commercial purposes only, as detailed in the figure below. Outcomes of the Pilot Testing Phase will be discussed with all Member States and relevant stakeholders and reviewed accordingly.

The documents used during this Pilot Testing Phase (Stream 1) for the non-commercial sharing of BMEPP through the WHO BioHub System are the following:

<table>
<thead>
<tr>
<th>SMTA 1</th>
<th>SMTA 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>(for contributions of BMEPP into the WHO BioHub System)</td>
<td>(for receipt of BMEPP from the WHO BioHub System)</td>
</tr>
<tr>
<td>Standard Material Transfer Agreement (SMTA) 1</td>
<td>Standard Material Transfer Agreement (SMTA) 2</td>
</tr>
<tr>
<td>Annex 1 to SMTA1 - Guiding Principles of the WHO BioHub System</td>
<td>Annex 1 to SMTA2 - Guiding Principles of the WHO BioHub System</td>
</tr>
<tr>
<td>Annex 2 to SMTA1 - Voluntary Transfer Form</td>
<td>Annex 2 to SMTA2 - Request Form</td>
</tr>
</tbody>
</table>

For information on the WHO BioHub System please visit: [https://www.who.int/initiatives/who-biohub/](https://www.who.int/initiatives/who-biohub/)
PILOT TESTING – WHO BIOHUB SYSTEM – STREAM 1
UNTIL MAY 2022

SMTA1 NON-COMMERCIAL PUBLIC HEALTH PURPOSES

WHO BioHub System
Standard Material Transfer Agreement 1 (SMTA)

for the Voluntary Sharing of Biological Materials with Epidemic or Pandemic Potential (BMEPP)¹ with a WHO BioHub Facility

Recitals

In furtherance of the Constitutional objective and functions of the World Health Organization (WHO),² and with a view to strengthening global epidemic and pandemic preparedness and response, WHO has established a voluntary system for biological materials with epidemic or pandemic potential (“BMEPP”³) at the WHO BioHub Facility listed below.

As more fully described in the WHO BioHub System Guiding Principles set out in Annex 1, the WHO BioHub System aims to protect and strengthen global public health security by providing one or more impartial, reliable, safe and secure WHO BioHub Facilities where WHO Member States can voluntarily send BMEPP, to facilitate timely risk assessment and dissemination of critical public health information, on the one hand, and, in due course, the rapid development of diagnostics, therapeutics and vaccines, as appropriate, for an effective, efficient, fair and equitable public health response, on the other.

This Standard Material Transfer Agreement 1, including its Annexes (the “Agreement”), sets forth the terms, conditions and modalities on which the Provider of BMEPP will voluntarily transfer BMEPP to a WHO BioHub Facility. This Agreement may be signed in advance of or at the time of the first shipment of BMEPP by the Provider into a WHO BioHub Facility. Subsequent shipments by the same Provider into the same or a different WHO BioHub Facility will be detailed in, and accompanied by, the WHO BioHub System Voluntary Transfer Form for Biological Materials with Epidemic or Pandemic Potential (BMEPP) found at Annex 2.

This Agreement is established to cover the “Pilot Testing Phase” of the WHO BioHub System project, only, and is therefore established for the limited scope and time duration set forth herein. If the WHO BioHub System project continues beyond the “Pilot Testing Phase” covered by this Agreement, including, as appropriate, based on input from WHO’s Member States, the Agreement may be extended and amended as appropriate by mutual agreement of the Parties.

¹ Please also complete the document found at Annex 2 to provide the details of the BMEPP being contributed.

² Including as set forth in Article 2, paragraphs (a)-(d), (f), (g), (j), (k) and (v) of the WHO Constitution.

³ For the purpose of the WHO BioHub System, the term BMEPP includes, without limitation, clinical specimens and cultured pathogens, whether wild-type or modified.
Article 1. Parties to the Agreement

This Agreement is entered into by and between:

[Name and address of the providing Member State], as represented by [__________] (the “Provider”);

[Name and address of the WHO BioHub Facility] (the “WHO BioHub Facility”); and

The World Health Organization, an international intergovernmental organization and the United Nations specialized agency for health, with its Headquarters at 20 avenue Appia, 1211 Geneva 27, Switzerland (“WHO”).

Each of the above is referred to herein from time to time as a “Party”, and together they are the “Parties”.

Article 2. Rights and obligations of the Provider

2.1 The Provider undertakes the following:

2.1.1 To provide BMEPP on a voluntary basis to the WHO BioHub Facility, in accordance with all relevant and applicable national laws and regulations, including those on access and benefit-sharing, for use by the WHO BioHub System on the terms, conditions and modalities specified herein; and

2.1.2 To ensure that the BMEPP are collected and handled in accordance with all applicable WHO, international, and national regulations and standards.4

2.2 In furtherance of the objectives of the WHO BioHub System, the Provider agrees to the onward transfer by the WHO BioHub Facility to, and use of the BMEPP by, any Qualified Entity for non-commercial purposes, in accordance with the terms, conditions and modalities, and for the purposes set out in this Agreement and other relevant and applicable WHO BioHub System policies, operating procedures and guidance.

2.3 Mindful that the WHO BioHub System is intended to complement, and not replace, existing or potential arrangements for sample sharing, the Provider retains the right to share other samples of the BMEPP with any other entity under the terms, conditions and modalities of its choice. Any such sharing is outside the scope of this Agreement.

4 This includes biosafety, biosecurity, applicable national laws, rules, and regulations on access and benefit-sharing, health regulations, relevant data protection laws or regulations related to the processing or use of genetic and personal data, and other relevant applicable laws, rules, regulations or standards.
Article 3. Rights and obligations of the WHO BioHub Facility

3.1 The WHO BioHub Facility undertakes the following with respect to the BMEPP:

3.1.1 To receive, store, grow, sequence and distribute upon request, the BMEPP solely for the purposes set out in the WHO BioHub System Guiding Principles set out in Annex 1 and pursuant to this Agreement;

3.1.2 To ensure that the BMEPP are handled in accordance with all applicable WHO, international, and national regulations and standards;

3.1.3 To upload BMEPP genetic sequence data that it generates, in a timely manner, to one or more publicly accessible genetic sequence databases (e.g. GISAID, INSDC Databases);

3.1.4 In the event of onward transfers of the BMEPP, to do so only to Qualified Entities that have concluded the relevant WHO BioHub System Standard Material Transfer Agreement (SMTA); and

3.1.5 To discuss and agree with WHO on the handling of any results arising from work on the BMEPP or otherwise directly arising from its work as a WHO BioHub Facility, including but not limited to the handling of intellectual property rights, prior to taking any steps to formalize or establish such rights, as far as this is not explicitly addressed herein. WHO in turn will discuss with the Provider if needed, in case of special situations that are not covered by the provisions of this Agreement.

Article 4. Rights and obligations of WHO

4.1. WHO will promote trust in, and usefulness of, the WHO BioHub System by, among other things, the following activities (including, as appropriate, during the Pilot Testing Phase):

4.1.1 Encouraging timely, voluntary sharing of BMEPP with a WHO BioHub Facility as soon as they are detected through national surveillance systems;

4.1.2 Monitoring operations of the WHO BioHub System and addressing issues as rapidly as possible, as they arise;

4.1.3 Further developing the WHO BioHub System, as necessary and appropriate, in particular ensuring that public health benefits are broadly made available, subject to availability of funds; and

5 This includes biosafety, biosecurity, applicable national laws, rules, and regulations on access and benefit-sharing, health regulations, relevant data protection laws or regulations related to the processing or use of genetic and personal data, and other relevant applicable laws, rules, regulations or standards.
4.1.4 Regularly and transparently providing reports on the status of the WHO BioHub System to Member States and partners.

4.2. WHO will be responsible to facilitate the funds required to cover the costs related to shipment of BMEPP to and from the WHO BioHub Facility pursuant to the terms of this Agreement during the Pilot Testing Phase.

**Article 5. Fair and equitable benefit sharing**

5.1 In furtherance of the aims set out in the Recitals of this Agreement, the WHO BioHub System aims to provide to all Member States and relevant partners, access to a range of public health information, tools, and products that may arise from the sharing of BMEPP with the WHO BioHub System. This Agreement covers the Pilot Testing Phase and period of the WHO BioHub System project, only, and that Pilot Testing Phase is not designed or intended to result in the creation of material benefits from the BMEPP. In the event that the use of BMEPP results in the creation of such material benefits, all Parties will engage with WHO to distribute and provide such benefits on a fair and equitable basis.

**Article 6. Intellectual property rights**

6.1 No Party should seek to obtain any intellectual property rights (IPRs) on the BMEPP.

6.2 The Parties acknowledge that any IPRs on the BMEPP obtained before the date of transfer of the BMEPP to the WHO BioHub Facility, will not be affected by this Agreement.

6.3 The Provider may have used technology protected by IPRs for the generation and/or modification of the BMEPP. The WHO BioHub Facility acknowledges that such IPRs shall be respected.

**Article 7. Warranties and responsibility**

7.1 The Provider warrants and represents that it has all rights, title, and permissions required to transfer the BMEPP pursuant to the terms of this Agreement, and assumes full responsibility for any third party claims thereby, and shall indemnify and hold harmless WHO and the WHO BioHub Facility for any claims related therein. Subject to the preceding, the Provider makes no warranties as to the safety of working with BMEPP, or as to the accuracy or correctness of any data provided with them, nor does the Provider make any warranties as to the quality, viability, or purity (genetic or mechanical) of the BMEPP being provided.

7.2 The Provider and the WHO BioHub Facility assume full responsibility for complying with all applicable international and national regulations, standards and rules as to import, export or release of BMEPP.

7.3 Each Party will be responsible for the manner in which it carries out its part of the activities under this Agreement, and the other Parties shall not be responsible for any other Party’s activities.
Article 8. Term, amendment, and termination

8.1 This Agreement will begin on signature by the authorized official of each Party. If the signing occurs on different dates, this Agreement will take effect on the date of the last dated signature.

8.2 This Agreement will continue until the end of the Pilot Testing Phase (as publicly stated by WHO) or 31 May 2022, whichever comes first.

8.3 This Agreement may be amended only by written agreement of the Parties.

8.4 Any Party may terminate this Agreement, subject to 180 days’ advance written notice to the other Parties. Any such termination will be without prejudice to the orderly completion of any ongoing activity pursuant to this Agreement as of the time of such notice of termination.

8.5 In the event of conclusion or early termination of this Agreement:

8.5.1 The Parties shall cease any and all use of the BMEPP and the WHO BioHub Facility will discuss with WHO the next steps in regard to the BMEPP;

8.5.2 The provisions of Articles 5 (Fair and equitable benefit sharing), Article 6 (Intellectual Property Rights), 7 (Warranties and responsibility), 8 (Term, amendment and termination), and 10 (Dispute resolution, no waiver of privileges and immunities, final provisions) shall survive for all Parties; and

8.5.3 The completion of activities related to this Agreement and any other matters arising therefrom shall be addressed by the Parties in good faith and consistent with the WHO BioHub System Guiding Principles.

8.6 At the end of the Pilot Testing Phase or 31 May 2022, whichever comes first, it is expected that a revised SMTA 1 will be available and the Provider undertakes to reasonably consider signing the new version of the SMTA 1, in which case such new version shall take precedence and control over this Agreement.
Article 9. Notifications and communications

9.1 Each Party will promptly notify the other Parties in writing of any anticipated or actual material changes that will affect the execution of this Agreement.

9.2 All written communications exchanged under this Agreement will be directed to the following addresses:

For the Provider: [    ]
cc. [    ]
[    ]
[    ]
[    ]

For the WHO BioHub Facility: [    ]
cc. [    ]
[    ]
[    ]
[    ]

For WHO: [    ]
cc. [    ]
World Health Organization
20 Avenue Appia
CH-1211 Geneva 27
Switzerland

9.3 Any Party may update their above-listed contact information by written notice to the other Parties.

Article 10. Dispute resolution, no waiver of privileges and immunities, final provisions

10.1 Any dispute relating to the interpretation or application of this Agreement shall, unless amicably settled, be resolved through mutual discussions and conciliation.

10.2 Nothing contained herein shall be construed as a waiver of any of the privileges and immunities enjoyed by WHO under national or international law, and/or as submitting WHO to any national court jurisdiction.

10.3 This Agreement sets forth the entire agreement of the Parties with respect to its subject matter. Any Annexes, Appendices and/or Exhibits attached to this Agreement are an integral part of this Agreement. In the event that any portion of this Agreement is held to be invalid for any reason, the remainder of this Agreement will remain in full force and effect. Paragraph headings in this Agreement are for reference only. This Agreement may be executed in one or more counterparts, each of which is an original, and all of which constitute a single instrument. Delivery of an executed Agreement by facsimile or by electronic delivery in portable document format (PDF) will be effective as delivery of a manually executed signature page of this Agreement.

[Signature page follows]
In WITNESS whereof, this Agreement has been duly executed by the Parties.

Accepted on behalf of the Provider: ______________________________
Name, Title: ______________________________
Place: ______________________________
Date: ______________________________

Accepted on behalf of the WHO BioHub Facility: ______________________________
Name, Title: ______________________________
Place: ______________________________
Date: ______________________________

Accepted on behalf of the World Health Organization: ______________________________
Name, Title: ______________________________
Place: ______________________________
Date: ______________________________

To be filled in by WHO

WHO Document Registration Number: SMTA_/__/202_/__/__
Introduction

The Guiding Principles set out below will guide implementation and operations of the voluntary system for the sharing of biological materials with epidemic or pandemic potential (“BMEPP”), known as the “WHO BioHub System”.

The WHO BioHub System aims to protect and strengthen global public health security by providing one or more impartial, reliable, safe and secure Facilities for BMEPP contributed by WHO Member States. The System aims to facilitate an effective, efficient, fair and equitable response to outbreaks through the rapid development of, inter alia, public health risk assessments on the one hand, and diagnostics, therapeutics and vaccines, as appropriate, on the other.

The objectives of the WHO BioHub System will be to:

a) Promote rapid and timely sharing of BMEPP;

b) Facilitate rapid access to such BMEPP and their information by relevant, interested, and qualified entities for the development of effective and safe public health products including diagnostics, vaccines and therapeutics; and

c) Ensure fair and equitable access to such products by all countries, based on public health needs.

Guiding Principles

**A voluntary system for the global public health**

All contributions of BMEPP to the WHO BioHub will be entirely voluntary, based on the desire for rapid generation of information and other resources for global public health.

**Timeliness**

To enable an effective public health response, the end-to-end system from sample collection to shipping and generation of scientific information must function with urgency. Data and analyses will be made publicly available in a timely manner, while respecting all applicable WHO, international, and national regulations and standards, and communicated promptly to decision-makers in the affected countries as well as more broadly to all WHO Member States to support effective and timely response measures.

**Equity and fairness**

Equity and fairness, as well as public health risk and need, will govern access to BMEPP contributed to the WHO BioHub System, and the research, data, and other materials resulting from the WHO BioHub System.
Transparency
Terms and conditions with respect to the use of BMEPP, sequence data and information from the WHO BioHub System will be made publicly available, as will criteria to receive BMEPP.

Acknowledgement and co-authorship
The contributions of collaborators to the WHO BioHub System, including laboratories providing BMEPP or genetic sequence data, will be appropriately acknowledged in presentations and publications, using guidelines such as those outlined by the International Committee of Medical Journal Editors. To the extent possible, entities using BMEPP in scientific research projects will seek the participation of scientists from the originating laboratory or countries and make efforts to engage them in preparation of manuscripts for presentation and publication.

Sustainability and maximal preservation
The BMEPP and associated data (e.g. epidemiological information) available through the WHO BioHub System will be critical for understanding diseases with epidemic or pandemic potential and developing tools to combat them. These important resources will need to be maintained and managed over the longer term. The WHO BioHub System will therefore be established and managed with longer term sustainability and maximal preservation in mind.

Collaboration & Cooperation
The WHO BioHub System will promote collaboration and cooperation with existing networks, repositories, and scientific groups to strengthen knowledge and contribute to the advancement of effective, efficient, fair and equitable response to epidemic or pandemic public health events.

Best practices for safety and security
The WHO BioHub System will follow procedures that ensure that BMEPP which are shared have been properly characterized, usually through culture and sequencing for pathogen materials. They will be prepared, dispatched, received, processed, stored and shipped to qualified recipients according to current, applicable national and international biosafety and biosecurity standards.

Consistency with applicable law
The WHO BioHub System will be established and operated in a manner consistent with applicable law, regulations, rules, and standards, including under legal rules and regulations as well as national and international law.

Consistency with applicable ethical regulations, norms, and standards requirements
The WHO BioHub System will be established and operated in a manner consistent with applicable WHO, international, and national ethical regulations, norms, and standards.
WHO BioHub System

Voluntary Transfer Form for SARS-CoV-2 BMEPP

This Voluntary Transfer Form will be revised by WHO, following a broad consultation process with Member States and other stakeholders.

This Voluntary Transfer Form must be completed, printed, signed and sent to WHO biohub@who.int. It should be included with the documents that accompany any requests for shipments of BMEPP into a WHO BioHub Facility.

==

I. General

1) This shipment is made in furtherance of the objectives of the WHO BioHub System from the WHO BioHub Facility located at: [Fill in the name of the WHO BioHub Facility].

2) BMEPP are part of a WHO system known as the ‘WHO BioHub System’ which aims to protect and strengthen global public health security by providing one or more impartial, reliable, safe and secure Facilities for biological materials with epidemic or pandemic potential (BMEPP) contributed by WHO Member States. The WHO BioHub System should facilitate an effective, efficient, fair and equitable response to outbreaks through the rapid development of diagnostics, therapeutics and vaccines, as appropriate.

3) The BMEPP in this shipment are provided on the condition that all terms and conditions applicable to BMEPP through the WHO BioHub System will apply.

4) This Annex contains three sections which should be completed as necessary by the concerned entity(ies).
II. Voluntary shipment of SARS-CoV-2 BMEPP into a WHO BioHub Facility

A) Information about the Provider Member State

<table>
<thead>
<tr>
<th>Name of Member State</th>
<th>Name of Focal Point to be contacted for BioHub purposes</th>
<th>Contact details (address, telephone and email)</th>
<th>Member State Public Health Laboratory</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

B) Additional Information about the Provider Member State relations with the WHO BioHub System

<table>
<thead>
<tr>
<th>1</th>
<th>The Provider has already signed an SMTA 1 with WHO and a WHO BioHub Facility</th>
<th>YES</th>
<th>NO</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 a</td>
<td>If YES, the Provider understands that the BMEPP are covered by the terms and conditions set out in the SMTA 1</td>
<td>□</td>
<td>□</td>
<td></td>
</tr>
</tbody>
</table>

C) Information about the SARS-CoV BMEPP shared in this shipment (This document is only for SARS-CoV-2 as this will be the sole type of BMEPP shared during the Pilot Testing Phase)

C.1) SARS-CoV-2 BMEPP shipping information

<table>
<thead>
<tr>
<th>BMEPP Number</th>
<th>Type of Material</th>
<th>Quantity (# of vials)</th>
<th>Amount/vial</th>
<th>Condition</th>
<th>Additional/Supporting Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
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<td>2.</td>
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<td>3.</td>
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</tr>
</tbody>
</table>

C.2) SARS-CoV-2 BMEPP clinical details

<table>
<thead>
<tr>
<th>BMEPP Number</th>
<th>Collection date</th>
<th>Location</th>
<th>Host</th>
<th>Gender</th>
<th>Patient age</th>
<th>Patient status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
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<td>2.</td>
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</tr>
<tr>
<td>3.</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
III. Acknowledgement of genetic sequence database for upload of BMEPP Genetic Sequence Data (GSD)

The WHO BioHub Facility will upload BMEPP GSD that it generates, in a timely manner, to one or more publicly accessible genetic sequence databases, including for example GISAID or INSDC. WHO will inform the Provider of the upload of GSD and will post the information on where the BMEPP has been uploaded, as part of the publicly available catalogue hosted on the WHO’s website.

This Voluntary Transfer Form has been completed on behalf of the Provider:

___________________________________
Name, Title: _________________________
Place: ______________________________
Date: ______________________________

To be filled in by WHO

WHO Document Registration Number:

SMTA_/__/202_/A2/202_/__/__/
WHO BioHub System

Standard Material Transfer Agreement 2 (SMTA) for the Sharing of Biological Materials with Epidemic or Pandemic Potential (BMEPP) with a Qualified Entity for non-commercial public health use

Recitals

In furtherance of the Constitutional objective and functions of the World Health Organization (WHO),\(^6\) and with a view to strengthening global epidemic and pandemic preparedness and response, WHO has established a voluntary system for biological materials with epidemic or pandemic potential (“BMEPP” \(^7\)) at the WHO BioHub Facility listed below.

As more fully described in the WHO BioHub System Guiding Principles set out in Annex 1, the WHO BioHub System aims to protect and strengthen global public health security by providing one or more impartial, reliable, safe and secure WHO BioHub Facilities where WHO Member States can voluntarily send BMEPP, to facilitate timely risk assessment and dissemination of critical public health information, on the one hand, and, in due course, the rapid development of diagnostics, therapeutics and vaccines, as appropriate, for an effective, efficient, fair and equitable public health response, on the other.

This Standard Material Transfer Agreement 2, including its Annexes (the “Agreement”), sets forth the terms, conditions and modalities by which a Qualified Entity will receive BMEPP from a WHO BioHub Facility, for non-commercial public health purposes only, as more fully detailed herein.

This Agreement is established to cover the “Pilot Testing Phase” of the WHO BioHub System project, only, and is therefore established for the limited scope and time duration as set forth herein. If the WHO BioHub System project continues beyond the “Pilot Testing Phase” covered by this Agreement, including, as appropriate, based on input from WHO’s Member States, the Agreement may be extended and amended as appropriate by mutual agreement of the Parties.

\(^6\) Including as set forth in Article 2, paragraphs (a)-(d), (f), (g), (j), (k) and (v) of the WHO Constitution.

\(^7\) For the purpose of the WHO BioHub System, the term BMEPP includes, without limitation, clinical specimens and cultured pathogens, whether wild-type or modified.
Article 1. Parties to the Agreement

1.1 This Agreement is entered into by and between:

[Name and address of the Qualified Entity] (the “Qualified Entity”); and

The World Health Organization, an international intergovernmental organization and the United Nations specialized agency for health, with its Headquarters at 20 avenue Appia, 1211 Geneva 27, Switzerland (“WHO”).

1.2 Each of the above is referred to herein from time to time as a “Party”, and together they are the “Parties”.

Article 2. Responsibilities of WHO

2.1. WHO will promote trust in, and usefulness of, the WHO BioHub System by, among other things, the following activities (including, as appropriate, during the Pilot Testing Phase):

2.1.1 Encouraging timely, voluntary sharing of BMEPP with a WHO BioHub Facility as soon as they are detected through national surveillance systems;

2.1.2 Monitoring operations of the WHO BioHub System and addressing issues as rapidly as possible, as they arise;

2.1.3 Further developing the WHO BioHub System, as necessary and appropriate; in particular ensuring that public health benefits are broadly made available, subject to availability of funds; and

2.1.4 Regularly and transparently providing reports on the status of the WHO BioHub System to Member States and partners.

2.2. WHO will be responsible to facilitate the funds required to cover the costs related to shipment of BMEPP to and from the WHO BioHub Facility pursuant to the terms of the relevant Agreement(s) (SMTA(s)) during the Pilot Testing Phase.

Article 3. Responsibilities of the Qualified Entity

3.1 The Qualified Entity assumes full responsibility for, and undertakes the following with respect to the BMEPP:

3.1.1 To receive the BMEPP and use them solely for the purposes selected below, as well as in accordance with the terms of this Agreement, and consistent with the WHO BioHub System Guiding Principles set out in Annex 1;
3.1.2 To ensure that the BMEPP are handled in accordance with all relevant and applicable WHO, international, and national regulations and standards, including rules as to the import and use;\textsuperscript{8}

3.1.3 Not to transfer the BMEPP to any other entity unless otherwise authorized or instructed to do so by WHO;

3.1.4 Not to seek intellectual property rights on the BMEPP;

3.1.5 To use the BMEPP solely for non-commercial public health purposes, including but not limited to risk assessment, surveillance activities, diagnostic applications and or quality assurance programmes (and consistent in all cases with paragraph 4.1 below);

3.1.6 To share with WHO, for broader dissemination, the results of analyses that may be of importance to public health for the understanding, prevention, or control of the disease caused by the BMEPP; and

3.1.7 To adhere to the Guiding Principles of the WHO BioHub System and ensure contributions of collaborators to the WHO BioHub System, including laboratories providing BMEPP or genetic sequence data, will be appropriately acknowledged in presentations and publications. To the extent possible, entities using BMEPP in scientific research projects will seek the participation of scientists from the originating laboratory or countries and make efforts to engage them in preparation of manuscripts for presentation and publication.

**Article 4. Fair and equitable benefit sharing**

4.1. In furtherance of the aims set out in the Recitals of this Agreement, the WHO BioHub System aims to provide to all Member States and relevant partners, access to a range of public health information, tools, and products that may arise from the sharing of BMEPP with the WHO BioHub System. This Agreement covers the Pilot Testing Phase and period of the WHO BioHub System project, only, and consistent with the provisions of Article 3 above, that Pilot Testing Phase is not designed or intended to result in the creation of material benefits from the BMEPP. In the event that the use of BMEPP results in the creation of such material benefits, the Qualified Entity will engage with WHO to distribute and provide such benefits on a fair and equitable basis.

\textsuperscript{8} This includes biosafety, biosecurity, applicable national laws, rules, and regulations on access and benefit-sharing, health regulations, relevant data protection laws or regulations related to the processing or use of genetic and personal data, and other relevant applicable laws, rules, regulations or standards, such as such as the current WHO biosafety and biosecurity criteria for BioHub.
Article 5. Warranties

5.1 The BMEPP will be provided by the WHO BioHub System through a designated WHO BioHub Facility, without any warranties as to their safety; the accuracy or correctness of any data provided with them; or their quality, viability, or purity (genetic or mechanical).

5.2 Each Party will be responsible for the manner in which it carries out its part of the activities under this Agreement, and the other Party will not be responsible for the other Party’s activities.

Article 6. Term, amendment, and termination

6.1 This Agreement will begin on signature by the authorized official of each Party. If the signing occurs on different dates, this Agreement will take effect on the date of the last dated signature.

6.2 This Agreement will continue until the end of the Pilot Testing Phase (as publicly stated by WHO) or 31 May 2022, whichever comes first.

6.3 This Agreement may be amended only by written agreement of the Parties.

6.4 Either Party may terminate this Agreement, subject to 180 days’ advance written notice to the other Party. Any such termination will be without prejudice to the orderly completion of any ongoing activity pursuant to this Agreement as of the time of such notice of termination. If a pandemic or epidemic due to a BMEPP that has been transferred to the Qualified Entity arises during such notice period, all obligations under this Agreement will survive and termination will take effect only after both fulfilment of the commitments by the Qualified Entity under the Requesting Form for Biological Materials with Epidemic or Pandemic Potential (BMEPP) applicable to each such transfer and the announcement of the end of the pandemic or epidemic.

6.5 In the event of conclusion or early termination of this Agreement:

6.5.1 The Qualified Entity shall cease any and all use of the BMEPP and will return any BMEPP in its possession to the WHO BioHub Facility that provided them, or destroy them (as advised by WHO);

6.5.2 The provisions of Articles 4 (Fair and equitable benefit sharing), 5 (Warranties), 6 (Term, amendment, and termination), and 8 (Dispute resolution, no waiver of privileges and immunities, final provisions) shall survive for all Parties; and

6.5.3 The completion of activities related to this Agreement and any other matters arising therefrom shall be addressed by the Parties in good faith and consistent with the WHO BioHub System Guiding Principles.

6.6 At the end of the Pilot Testing Phase or 31 May 2022, whichever comes first, it is expected that a revised SMTA 2 will be available and the Qualified Entity undertakes to reasonably consider signing the
new version of the SMTA 2, in which case such new version shall take precedence and control over this Agreement.

Article 7. Notifications and communications

7.1 Each Party will promptly notify the other Parties in writing of any anticipated or actual material changes that will affect the execution of this Agreement.

7.2 All written communications exchanged under this Agreement will be directed to the following addresses:

For the Qualified Entity:
[ ]
cc. [ ]
[ ]
[ ]

For WHO:
[ ]
cc. [ ]
World Health Organization
20 Avenue Appia
CH-1211 Geneva 27, Switzerland

7.3 Any Party may update their above-listed contact information by written notice to the other Parties.

Article 8. Dispute resolution, no waiver of privileges and immunities, final provisions

8.1 Any dispute relating to the interpretation or application of this Agreement shall, unless amicably settled, be resolved through mutual discussions and conciliation.

8.2 Nothing contained herein shall be construed as a waiver of any of the privileges and immunities enjoyed by WHO under national or international law, and/or as submitting WHO to any national court jurisdiction.

8.3 This Agreement sets forth the entire agreement of the Parties with respect to its subject matter. Any Annexes, Appendices and/or Exhibits attached to this Agreement are an integral part of this Agreement. In the event that any portion of this Agreement is held to be invalid for any reason, the remainder of this Agreement will remain in full force and effect. Paragraph headings in this Agreement are for reference only. This Agreement may be executed in one or more counterparts, each of which is an original, and all of which constitute a single instrument. Delivery of an executed Agreement by facsimile or by electronic delivery in portable document format (PDF) will be effective as delivery of a manually executed signature page of this Agreement.

[Signature page follows]
In WITNESS whereof, this Agreement has been duly executed by the Parties.

Accepted on behalf of the
World Health Organization:                            Accepted on behalf of the
Qualified Entity:

___________________________________                        __________________________________
Name, Title: ____________________________                     Name, Title: ____________________________
Place: ________________________________                         Place: ________________________________
Date: ________________________________                         Date: ________________________________

To be filled in by WHO

WHO Document Registration Number:

SMTA_/__/202_/__/__
Introduction

The Guiding Principles set out below will guide implementation and operations of the voluntary system for the sharing of biological materials with epidemic or pandemic potential (“BMEPP”), known as the “WHO BioHub System”.

The WHO BioHub System aims to protect and strengthen global public health security by providing one or more impartial, reliable, safe and secure Facilities for BMEPP contributed by WHO Member States. The System aims to facilitate an effective, efficient, fair and equitable response to outbreaks through the rapid development of, inter alia, public health risk assessments on the one hand, and diagnostics, therapeutics and vaccines, as appropriate, on the other.

The objectives of the WHO BioHub System will be to:

a) Promote rapid and timely sharing of BMEPP;

b) Facilitate rapid access to such BMEPP and their information by relevant, interested, and qualified entities for the development of effective and safe public health products including diagnostics, vaccines and therapeutics; and

c) Ensure fair and equitable access to such products by all countries, based on public health needs.

Guiding Principles

A voluntary system for the global public health
All contributions of BMEPP to the WHO BioHub will be entirely voluntary, based on the desire for rapid generation of information and other resources for global public health.

Timeliness
To enable an effective public health response, the end-to-end system from sample collection to shipping and generation of scientific information must function with urgency. Data and analyses will be made publicly available in a timely manner, while respecting all applicable WHO, international, and national regulations and standards, and communicated promptly to decision-makers in the affected countries as well as more broadly to all WHO Member States to support effective and timely response measures.

Equity and fairness
Equity and fairness, as well as public health risk and need, will govern access to BMEPP contributed to the WHO BioHub System, and the research, data, and other materials resulting from the WHO BioHub System.

Transparency
Terms and conditions with respect to the use of BMEPP, sequence data and information from the WHO BioHub System will be made publicly available, as will criteria to receive BMEPP.
Acknowledgement and co-authorship
The contributions of collaborators to the WHO BioHub System, including laboratories providing BMEPP or genetic sequence data, will be appropriately acknowledged in presentations and publications, using guidelines such as those outlined by the International Committee of Medical Journal Editors. To the extent possible, entities using BMEPP in scientific research projects will seek the participation of scientists from the originating laboratory or countries and make efforts to engage them in preparation of manuscripts for presentation and publication.

Sustainability and maximal preservation
The BMEPP and associated data (e.g. epidemiological information) available through the WHO BioHub System will be critical for understanding diseases with epidemic or pandemic potential and developing tools to combat them. These important resources will need to be maintained and managed over the longer term. The WHO BioHub System will therefore be established and managed with longer term sustainability and maximal preservation in mind.

Collaboration & Cooperation
The WHO BioHub System will promote collaboration and cooperation with existing networks, repositories, and scientific groups to strengthen knowledge and contribute to the advancement of effective, efficient, fair and equitable response to epidemic or pandemic public health events.

Best practices for safety and security
The WHO BioHub System will follow procedures that ensure that BMEPP which are shared have been properly characterized, usually through culture and sequencing for pathogen materials. They will be prepared, dispatched, received, processed, stored and shipped to qualified recipients according to current, applicable national and international biosafety and biosecurity standards.

Consistency with applicable law
The WHO BioHub System will be established and operated in a manner consistent with applicable law, regulations, rules, and standards, including under legal rules and regulations as well as national and international law.

Consistency with applicable ethical regulations, norms, and standards requirements
The WHO BioHub System will be established and operated in a manner consistent with applicable WHO, international, and national ethical regulations, norms, and standards.
WHO BioHub System

Request Form for SARS-CoV-2 BMEPP

This Request Form will be revised by WHO, following a broad consultation process with Member States and other stakeholders.

This Request Form must be completed, printed, signed and sent to WHO biohub@who.int. It should be included with the documents that accompany any requests for shipments of BMEPP from a WHO BioHub Facility to a Qualified Entity for non-commercial purposes. Shipments out of a WHO BioHub Facility will be made following a request received from a Qualified Entity that meets all required biosafety and biosecurity requirements for the BMEPP requested.

= = =

I. General

1) This shipment is made in furtherance of the objectives of the WHO BioHub System from the WHO BioHub Facility located at: [Fill in the name of the WHO BioHub Facility].

2) BMEPP are part of a WHO system known as the ‘WHO BioHub System’ which aims to protect and strengthen global public health security by providing one or more impartial, reliable, safe and secure Facilities for biological materials with epidemic or pandemic potential contributed by WHO Member States. The WHO BioHub System should facilitate an effective, efficient, fair and equitable response to outbreaks through the rapid development of diagnostics, therapeutics and vaccines, as appropriate.

3) The BMEPP in this shipment are provided on the condition that all terms and conditions applicable to BMEPP through the WHO BioHub System will apply.

4) This Annex contains four sections which should be completed as necessary by the concerned entity(ies).
II. Qualified Entity requesting SARS-CoV-2 BMEPP from a WHO BioHub Facility

<table>
<thead>
<tr>
<th>Name of Qualified Entity</th>
<th>Name of Focal Point to be contacted for BioHub purposes</th>
<th>Contact details (address, telephone and email)</th>
<th>Member State Public Health Laboratory</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
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</table>

III. Information about the SARS-CoV-2 BMEPP requested in this shipment

<table>
<thead>
<tr>
<th>BMEPP Name</th>
<th>WHO Catalog BMEPP registration number*</th>
<th>Amount/vial</th>
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<tbody>
<tr>
<td>1.</td>
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<td>2.</td>
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<td>3.</td>
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</table>

*Please visit the WHO Webpage https://www.who.int/initiatives/who-biohub/
For shipping arrangement, a specific booking form will be provided

IV. Conditions for shipment of SARS-CoV-2 BMEPP by a WHO BioHub Facility to a Qualified Entity

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
<th>Comments</th>
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<td>The recipient Qualified Entity warrants that it meets applicable biosafety &amp; biosecurity standards for the respective BMEPP as per the WHO guidance in this area. <strong>Note</strong>: By filling in this Annex, the Qualified Entity commits to a dynamic self re-evaluation of the biosecurity and biosafety risks, based on their (self-assessed) risk level, and consult WHO specifically in case of doubt or if Dual Use Research of Concern is contemplated.</td>
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<td></td>
<td>The Qualified Entity has signed an SMTA 2</td>
<td></td>
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</tr>
</tbody>
</table>

|   | The Qualified Entity agrees with the Guiding Principles of the WHO BioHub System | |

| 3.a | The Qualified Entity will endeavour to ensure participation of Provider scientists, especially those from developing countries, to the fullest extent possible, in scientific projects associated with research on BMEPP from their countries and active engagement of such scientists in the preparation of manuscripts for presentation and publication. The Qualified Entity agrees to ensure appropriate acknowledgement in presentations and publications, of the contributions from BMEPP Provider scientists using existing scientific guidelines. | ☐ | ☐ |

This Request Form has been completed on behalf of the **Qualified Entity**:

__________________________________________

Name, Title: ____________________________

Place: ________________________________

Date: ________________________________

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To be filled in by WHO

**WHO Document Registration Number:**

SMTA_/__/202_/A2/202_/__/__