World Health Organization

Memorandum of Understanding

between

the Swiss Confederation

represented by the Swiss Federal Office of Public Health acting on behalf of the Swiss Federal Department of Home Affairs (FDHA)

together with

the Swiss Federal Office for Civil Protection acting on behalf of the Swiss Federal Department of Defence, Civil Protection and Sport (DDPS)

and

the World Health Organization

regarding

the Cooperation of the Signatories on the World Health Organization (WHO) BioHub System

Introduction

WHEREAS, the Swiss Federal Department of Home Affairs (FDHA) represented by the Federal Office of Public Health of the Swiss Confederation (the "FOPH"), is the Swiss Federal Government's centre for public health, the Swiss Federal Department of Defence, Civil Protection and Sport (DDPS) represented by Spiez Laboratory, is a division of the Swiss Federal Office for Civil Protection (the "FOCP"), both acting on behalf of the Swiss Confederation, and the Spiez Laboratory is the Swiss Federal Institute for Nuclear, Biological and Chemical (NBC) Protection;

WHEREAS, the World Health Organization ("WHO"), having its headquarters in Geneva, Switzerland, is the directing and coordinating authority on international health and the United Nations specialized agency for health;

WHEREAS, WHO is establishing a WHO-led biorepository system to facilitate the voluntary sharing by WHO Member States of biological materials with epidemic or pandemic potential, including to facilitate an effective, efficient, fair and equitable response to outbreaks, including through the rapid development of diagnostic, therapeutics and vaccines, as appropriate (the "WHO BioHub System"), as further detailed in the description set forth in Annex I hereto;

WHEREAS the FOPH and the FOCP wish to support the development and operation of the WHO BioHub System, including by providing resources and the facilities of the Spiez Laboratory;

WHEREAS, WHO, the FOPH and the FOCP (the "Signatories") wish to establish this Memorandum of Understanding (the "MOU") to clarify the modalities of their support for, and the Signatories cooperation regarding, the WHO BioHub System and their cooperation; and

WHEREAS, nothing in this MOU prejudges in any way the views and position of Switzerland on issues related to the WHO BioHub System or to pathogen sharing, including in the ongoing and future work of WHO on such issues;

Now, therefore, the Signatories decide as follows:

Article 1
Objectives and Areas of Cooperation

1. The objective of this MOU is to facilitate collaboration between the Signatories regarding the establishment and implementation of the WHO BioHub System, including at the FOCP. While the focus of this MOU at the time of signature is on the work of the FOCP, the Signatories note that the WHO BioHub System may include additional laboratory sites or working arrangements.

2. In furtherance of the above objective, the Swiss Confederation agrees to contribute the necessary resources to support its work for the WHO BioHub System during its first period of establishment and implementation, through 31 March 2024, and, if mutually agreed by the Signatories, for a further duration. As part of this support, the Swiss Confederation agrees to be responsible for costs (including administrative costs) related to the Spiez laboratory's work for the WHO BioHub System during this first period.

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3. The areas of cooperation listed herein are not exhaustive and should not be taken to exclude or replace other forms of cooperation between the Signatories on other issues of common interest.

Article 2
Organization and Implementation of the Cooperation

1. Mindful of the phased development of the WHO BioHub System, the Signatories intend for this MOU to be a 'living document' and for this collaboration to be one of regular discussion and dialogue. In that regard, WHO will keep the Signatories apprised of developments regarding the WHO BioHub System, including regarding the development of any relevant documents that will govern the use and onward sharing of the materials and operation of the WHO BioHub System referred to in Annex I Paragraph 2 and 3, and will consult with the Signatories prior to any material revisions that would affect the collaboration under this MOU.

2. Specifically, the Signatories intend to hold joint meetings regarding this MOU and their collaboration regarding the WHO BioHub System on a regular basis, including by teleconference, videoconference, and face-to-face meetings, as appropriate, to evaluate progress, and to make recommendations between the Signatories, as appropriate. An annual high-level meeting is also expected to take place to take stock of the collaboration and joint activities, define and reorient priority areas of collaboration, as needed.

3. Implementation of the collaboration described in this MOU will be subject to the availability of sufficient financial and human resources for that purpose, as well as each Signatory's programme of work, priority activities, policies, rules and regulations, as well as its administrative procedures and practices.

4. This MOU does not provide for any transfer of funds between the Signatories, and any such transfer of funds would be subject to a separate agreement between them.

Article 3
Intellectual Property Rights

1. Each Signatory maintains any pre-existing intellectual property rights (IPRs) and any IPRs resulting from its own activities under this MOU (noting the provisions of paragraph 2 below). In the event any joint activities pursuant to this MOU result in IPRs, the provisions regarding such IPRs will be determined by separate agreement between the Signatories prior to the dissemination of such IPRs.

2. For clarity, the Signatories note that IPRs resulting from activities under the WHO BioHub System will be addressed in the relevant documents and arrangements that will govern the use and onward sharing of the materials and operation of the WHO BioHub System, and are not addressed in the scope of this MOU.

Article 4
Official Emblems and Logos

No Signatory will use the name, emblem, logo, or trademark of any other Signatory, its subsidiary bodies, or affiliates, in any way, including in any publication or public document, without the prior written approval of that other Signatory.

Article 5
Disclosure and Publicity

1. Subject to the provisions of Article 4 above, each Signatory may acknowledge the existence of this MOU to the public, as well as to the extent possible, general information with respect to the collaborative activities contemplated herein. Such disclosure will be made in accordance with the disclosing Signatory's respective disclosure policies, provided always that any such disclosure will be consistent with the terms of this MOU.

2. Each Signatory may publish this MOU on its website, provided that the context in which each Signatory intends to do so will be subject to the advance written agreement of the other Signatory (agreement not to be unreasonably withheld), and except as explicitly provided herein, this MOU and any subsequent agreements and/or any individual clauses contained therein will not be publicly disclosed or made available without the prior written agreement of both Signatories.

Article 6
Responsibility

Each Signatory will be solely responsible for the manner in which it carries out its part of the activities under this MOU. Thus, a Signatory will not be responsible for any loss, accident, damage or injury suffered or caused by another Signatory, or that other Signatory's personnel or contractors, in connection with, or as a result of, the collaboration under this MOU.

Article 7
Notification and Amendment

1. Each Signatory will promptly notify the other Signatories in writing of any anticipated or actual material changes that will affect the execution of this MOU.

2. This MOU may be amended only by mutual written agreement of the Signatories.

Article 8
Duration and Termination

1. This MOU will begin on signature by the authorized official of each Signatory. If the signing occurs on different dates, this MOU will take effect on the date of the last signature thereof.

2. This MOU will continue until 31 March 2024, and may be extended at that time by written agreement of the Signatories for additional periods of three years.

3. Either Signatory may terminate this MOU subject to three (3) months' advance written notice to the other Signatories. Any such termination will be without prejudice to the orderly completion of any ongoing activity pursuant to this MOU as of the time of such notice of termination.

Article 9
Communications

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

For the FOPH:
Nora Kronig Romero
Vice-Director, Head International Affairs Division
cc. Isabel Streit, WHO Adviser for Switzerland

Federal Office of Public Health of the Swiss Confederation
Schwarzenburgstrasse 157
CH-3003 Bern
Switzerland

For WHO:
Dr Sylvie Briand
Director Global Infectious Hazards Preparedness Department
WHO Health Emergencies Programme
World Health Organization
20 Avenue Appia
CH-1211 Geneva 27
Switzerland

For the FOCP:
Dr Marc Cadisch
Director Spiez Laboratory
cc: Dr Isabel Hunger-Glaser, Head Biology Division

Spiez Laboratory
Austrasse
CH-3700 Spiez
Switzerland

Article 10
Other Matters

1. In the event of a divergence of opinion arising out of or relating to this MOU, the Signatories will use their best efforts to promptly resolve such matter amicably through direct conversations. Any such controversy or dispute, which is not settled amicably as described above, may be referred by either party to arbitration in accordance with the UNCITRAL Arbitration rules then in force. The place of arbitration shall be Geneva and the language shall be English. The Signatories shall be bound by an arbitration award rendered as a result of such arbitration as the

final adjudication of such dispute. The arbitral tribunal shall have no authority to award punitive damages.

2. Nothing contained herein will be construed as a waiver of any of the privileges and immunities enjoyed by WHO in conformity with the Agreement of 21 August 1948 between the Swiss Federal Council and WHO regarding the legal status of WHO in Switzerland (RS 0.192.120.281), or as submitting WHO to any national court jurisdiction.

3. This MOU is signed in both the English and French languages. In the event of any inconsistency between the versions in those languages, the English version controls.

Signed in duplicate on the date provided below:

For the **Swiss Confederation**

Alain Berset
Federal Councillor
Head Federal Department of Home Affairs (FDHA)
Date: 24.05.2021

Viola Amherd
Federal Councillor
Head Federal Department of Defence, Civil Protection and Sport (DDPS)
Date: 26.5.2021

For the **World Health Organization**

Dr Tedros Adhanom Ghebreyesus
Director-General
Date: 24 May 2021

Annex I

WHO BioHub System: Description and Guiding Principles

This Annex provides detailed information on the WHO BioHub System as of 16 April 2021, mindful, as mentioned in the body of the MOU, that the System's development is a dynamic process, and the MOU is, therefore, intended to be a "living document", and this Annexure may be updated and supplemented and revised as appropriate by agreement (exchange of letters) of the Signatories.

1. Purpose and objectives of the BioHub System

The WHO BioHub System aims to protect and strengthen global public health security by providing one or more neutral, reliable, safe and secure facilities for biological materials with epidemic or pandemic potential ("BMEPP") contributed by WHO Member States. The System should facilitate an effective, efficient, fair and equitable response to outbreaks through the rapid development of diagnostics, therapeutics and vaccines, as appropriate.

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.

2. Development process for the WHO BioHub System

The WHO BioHub System will be based on the Guiding Principles detailed in part 3, below. The System will build on existing WHO networks of laboratories, such as the Global Influenza Surveillance and Response System (GISRS).

Development is proceeding in a phased manner: in the first phase that will start in the first half of 2021, WHO anticipates that the WHO BioHub System, through its facilities, will receive, store, grow, sequence and distribute to qualified entities that meet applicable national and international regulations and rules, and agree to the terms, conditions and modalities to be established by WHO biological material from the SARS-CoV-2 variants.

During this development, WHO will develop other relevant documents that will govern the use and onward sharing of the materials and operation of the WHO BioHub System, including Standard Material Transfer Agreements (SMTAs), Standard Operating Procedures (SOPs), and Terms of Reference with Spiez Laboratory.

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3. *Guiding Principles for the WHO BioHub System*

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 and 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 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.

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