

GH-VAP DATA SHARING GUIDING PRINCIPLES

A. Overview and Objectives

1. The Global Health Vaccine Accelerator Program (“GH-VAP”) is intended to accelerate vaccine translation for several infectious diseases.
2. The GH-VAP is intended to leverage existing infrastructure from the Collaboration for AIDS Vaccine Discovery (“CAVD”) and to provide broader access to select GH-VAP platforms funded by the Bill & Melinda Gates Foundation (“Foundation”) so as to:
 - a. Increase platform visibility for partners of the Foundation;
 - b. Standardize conditions and agreements for access to data; and
 - c. Facilitate tracking of data requests for users, providers and the Foundation
3. An objective of the GH-VAP – like all projects funded by the Bill & Melinda Gates Foundation (Foundation) - is to ensure that the project and any resulting products, services, processes, technologies, materials, software, data or other innovations (collectively, “Funded Developments”) are managed in a manner that ensures “Global Access.” Global Access requires that (a) the knowledge and information (including data) gained from the Project be promptly and broadly disseminated and (b) the Funded Developments be made available and accessible at an affordable price to people most in need within developing countries.
4. Application of these GH-VAP data sharing guiding principles (the “Principles”) shall only apply to Data generated by GH-VAP Projects.
5. GH-VAP Members are the organizations that have agreed to and signed the Principles Agreement and include GH-VAP Platform Partners and GH-VAP Platform Recipients.

B. Definitions

1. **GH-VAP Platform Partners** (“GH-VAP PPs”) are organizations who have agreed to participate in the GH-VAP and provide a service, scientific expertise, or access to a research platform in support of the GH-VAP. These organizations have agreed to the Principles as applied to GH-VAP Projects and are listed at the following page of the GH-VAP Portal: https://portal.ghvap.org/Lists/Platform_Partners. The Foundation will establish an initial list of GH-VAP PPs and may modify that list from time to time. The Foundation will notify all GH-VAP Members of any such modifications.
2. **Data** means recorded information generated in the performance of a GH-VAP

Project under a GH-VAP Platform, including Data related to gene sequences.

3. **GH-VAP Platform Recipients** (“GH-VAP PRs”) are organizations having investigators that desire to be considered for funding by BMGF and gain facilitated access to GH-VAP PPs by submitting a request through the GH-VAP web portal. Approved requests lead to the development of a Statement of Work by the GH-VAP PR investigator, GH-VAP PP and BMGF. When described as taking any action related to a GH-VAP Project (including, without limitation, receiving notices or providing permissions), GH-VAP PRs will take such action through the GH-VAP PR’s Principal Investigator. GH-VAP PRs are listed at the following page of the GH-VAP Portal: [https://portal.ghvap.org/Lists/Platform Recipients](https://portal.ghvap.org/Lists/Platform%20Recipients). Each of the GH-VAP PRs will conclude an agreement with the Foundation that describes how Global Access will be achieved for the GH-VAP Projects they participate in. The Foundation will establish the initial list of GH-VAP PRs and the list may be updated from time to time by the Foundation. The Foundation will notify the GH-VAP Funded GH-VAP PRs of any such updates.
4. **GH-VAP Portal** is a web interface and associated functionality and storage through which GH-VAP PRs will (i) request access to the platforms and related services and expertise provided by the GH-VAP PPs and (iii) be provided access to stored documents established by GH-VAP PPs. The GH-VAP Portal (<https://portal.ghvap.org>) will store signed versions of these Principles and the GH-VAP SOW. GH-VAP PPs may also keep separately a signed version of the Principles, the GH-VAP SOW, GH-VAP Cost Estimate and any research agreement or material transfer agreement.
5. **GH-VAP Projects** are research projects for which a GH-VAP SOW exists and which the relevant GH-VAP PPs, GH-VAP PRs and Foundation have agreed to and signed.
6. **GH-VAP Statement of Work** (“GH-VAP SOW”) is the technical description of a GH-VAP Project (including the Materials, experimental design, deliverables, and timelines) to be undertaken by a GH-VAP PR and GH-VAP PP and agreed to by the Foundation, GH-VAP PP, and GH-VAP PR. An agreed-to GH-VAP SOW will be stored in the GH-VAP Portal.
7. **GH-VAP Cost Estimate** contains the estimated costs for all activities represented in the Statement of Work. This GH-VAP Cost Estimate is generated by the GH-VAP PP and provided to the Foundation for review and approval before proceeding with the implementation of the GH-VAP SOW. Unless otherwise agreed by the GH-VAP PP concerned, this information is not shared with the GH-VAP PR and/or GH-VAP Members.
8. **Global Access Objectives** means that GH-VAP Projects will be conducted and managed – along with the resulting products, services, processes, technologies, materials, software, data or other innovations (collectively, “Funded

Developments”) – in a manner that ensures “Global Access.” Global Access requires that (a) the knowledge, information, and data gained from GH-VAP Projects be promptly and broadly disseminated and (b) the Funded Developments be made available and accessible at an affordable price to people most in need within developing countries.

9. **Materials** will be defined in each of the research agreement or material transfer agreement that is the legal instrument used by GH-VAP PRs to transfer Materials to a GH-VAP PP in the conduct of a GH-VAP Project.
10. **Publish or Publishing** means the act of communicating to the public, whether through publications, presentations, posters or otherwise, and whether by text or images via written, verbal or electronic means (with such means being referred to collectively as **Publications**).

C. Principles

1. Each GH-VAP PR acknowledges that they are required to share Data with other GH-VAP Members and with the Foundation in accordance with the terms of these Principles, including the GH-VAP Confidential Disclosure Agreement (Annex B).
2. No GH-VAP PR shall assert database rights, copyrights, or other rights in Data to interfere with another GH-VAP Member or the Foundation in implementing a GH-VAP Project. GH-VAP PPs agree not to assert patent rights against GH-VAP Members that are engaged in activities within the scope of a GH-VAP SOW.
3. Data must be collected, maintained and used in accordance with the necessary informed consent and regulatory approval (if applicable) in support of these Principles.
4. The GH-VAP PPs, and GH-VAP PRs will work with the Foundation to determine the process by which Materials and/or Data will be physically or electronically transferred among the GH-VAP PRs and the Foundation, in accordance with the following principles:
 - a. Costs associated with material and/or data sharing activities, including costs to ensure that the data is in a form compliant with applicable laws (eg anonymized), and “Open Access” publications specified in these principles will be incorporated into the budget and the grant agreement.
 - b. Each GH-VAP PP will develop one or more research agreements or material transfer agreements to enable such transfers of materials or Data between the GH-VAP PRs and GH-VAP PPs. The Foundation will determine if the research agreements or material transfer agreements are consistent with these Principles before they stored in the GH-VAP Portal for use in GH-VAP

Projects. For a given GH-VAP Project, the GH-VAP PP will determine which research agreement or material transfer agreement should be provided to GH-VAP PR participating in the GH-VAP Project. GH-VAP PPs agree that any inconsistency between these Principles and a research or material transfer agreement as used in a GH-VAP Project will be resolved in favor of these Principles.

- c. The GH-VAP PR for which a GH-VAP PP generated Data under GH-VAP Project will be obliged to share the Data with other GH-VAP Members and the Foundation following a reasonable period of time not to exceed the first or second periods as follows:
 - i. First Period of Delay of Data Sharing: not to exceed six months following receipt of the Data by GH-VAP PR or until the day a manuscript generated from the data is published, whichever comes first; and
 - ii. An Extended Period of Delay of Data Sharing: in the event that the Data is antigen sequence information to be used in a formulation or a specific formulation itself and the GH-VAP PR or GH-VAP PP concerned intends to make use of the Data when seeking patent protection, the period of delay may be extended subject to the following:
 - iii. The Extended Period of Delay will expire at the end of any in vivo studies that are underway or planned to generate the Data if such studies will extend beyond the First Period, but in any case not to exceed a cumulative total of eighteen (18) months following receipt of the Data by the GH-VAP PR.
 - iv. Notwithstanding the foregoing, a GH-VAP PR or GH-VAP PP taking advantage of the Extended Period of Delay shall submit Blinded Data for sharing with the other GH-VAP PRs. "Blinded" Data shall mean that the exact identity of the material that was the subject of the study that gave rise to the Data is generically disclosed by descriptor.
- d. For Data where standardized data formats, metadata standards and repositories exist, such as for certain genomic and transcriptomic data, the GH-VAP PR will provide the Foundation and other GH-VAP Members an appropriate link and identifier (e.g. accession number) to the data. A list of publicly available repositories is listed in Annex A.
- e. Investigators that wish to submit data to repositories that aren't listed in Annex A should provide the Foundation with links and information regarding the unlisted repository. The Foundation will discuss with the relevant investigator as to whether the unlisted repository meets the Data access requirements of these Principles and, if so, it will be circulated to the GH-VAP PRs and GH-VAP PPs and, if there are no objections within ninety (90) days, it will be added to Annex A.
- f. For Data where standardized data formats, metadata standards and repositories do not presently exist, the PO will work with the grantee to establish necessary and appropriate formats, standards, and identify or

- establish a repository by which the Data will be shared.
- g. When Data is Published or otherwise publicly disseminated by GH-VAP Members, any entity which Published or otherwise publically disseminated the Data is required to acknowledge the GH-VAP PP that generated the Data and GH-VAP PR that requested the services that led to the generation of the Data.
 - h. Prior to Publishing on Data generated under a GH-VAP Project, the GH-VAP Member that is the author of the Publication must provide a copy of the manuscript to the GH-VAP PP or GH-VAP PR that generated or requested the Data at least thirty (30) days prior to submission for publication and shall reasonably consider any comments provided.
 - i. Authorship guidelines will be in accordance with those of the International Committee of Medical Journal Editors, or other generally recognized standards.
 - j. All publications on Data generated under a GH-VAP Project shall be on “open access” terms and conditions whereby users of such publications would be free to copy and redistribute them in any medium or format and transform and build upon the Data for any purpose (including commercial) without further permission or fees being required. Such “open access” to the Data itself does not require or imply a license to or waiver of patent rights held by a GH-VAP Member.

SIGNATORY
to the
GH-VAP DATA SHARING GUIDING PRINCIPLES

IN WITNESS WHEREOF, the undersigned GH-VAP Member hereby executes the GH-VAP Principles, which includes an agreement to be bound by the terms of the Master GH-VAP Confidential Disclosure Agreement (Annex B).

Signed on Behalf of (Identify Organization):

By: _____

Name: _____

Title: _____

Date Signed: _____

[Separate signature pages to be completed by Each GH-VAP Member.]

Annex A – List of publicly available data repositories

Publicly available repositories that are in compliance with the data sharing requirements set forth in the GH-VAP DSA.

- **GenBank** - <http://www.ncbi.nlm.nih.gov/genbank/>
- **International Nucleotide Sequence Database Collaboration** - <http://www.insdc.org/>
- **HIV Sequence Database** - <http://www.hiv.lanl.gov/content/sequence/HIV/mainpage.html>
- **HIV Molecular Immunology Database** - <http://www.hiv.lanl.gov/content/immunology/index>. The HIV Molecular Immunology Database is an annotated, searchable collection of HIV-1 cytotoxic and helper T-cell epitopes and antibody binding sites.
- **Nonhuman Primate HIV/SIV Vaccine Trials Database** - <http://www.hiv.lanl.gov/content/vaccine/home.html>. This database, funded by the National Institutes of Health, contains information about vaccine studies using SIV and HIV in nonhuman primates.
- **Hepatitis C Virus (HCV) Database Project** - <http://hcv.lanl.gov/content/index>
- **Hemorrhagic Fever Viruses (HFV) Database Project** - <http://hfv.lanl.gov/content/index>
- **ImmPort** - <https://import.niaid.nih.gov/importWeb/>
- **GigaDB** – www.gigadb.org (under consideration)

Annex B

MASTER GH-VAP CONFIDENTIAL DISCLOSURE AGREEMENT

WHEREAS, the GH-VAP Platform Partners (GH-VAP PPs) and GH-VAP Platform Recipients (GH-VAP PRs) (herein referred to collectively as “GH-VAP Members”) anticipate that any exchange of Confidential Information (as defined below) will be in accordance with the terms of this Master GH-VAP Confidential Disclosure Agreement (Master CDA).

WHEREAS, All GH-VAP Members are a party to the GH-VAP Data Sharing Guiding Principles (the “Guiding Principles”) and any inconsistency between this Master CDA and the Agreement will be resolved in favor of the Agreement.

WHEREAS, the GH-VAP Members are interested in examining and evaluating the other party’s Confidential Information for the purpose of carrying out their own activities within the corresponding **GH-VAP Project(s)** (the “**Purpose**”).

Now, therefore, the GH-VAP Members agree to the following terms and conditions with respect to the transfer of Confidential Information between GH-VAP Members.

DEFINITIONS

Affiliate means any business entity controlled by, controlling or under common control of a GH-VAP Member. Such control shall include beneficial ownership of more than fifty percent (50%) of the voting interest in an entity, or such other relationship as, in fact, constitutes actual control.

Confidential Information means (subject to Section 4):

- (i) all information related to the Purpose contained in a document (either physical or electronic) that is marked “Confidential” or that bears a similar legend, heading or watermark, including, but not limited to, information regarding data, inventions, know-how, ideas, procedures, formulations, compounds, biologics, designs, formulae, methods, techniques, financial projections and/or terms, software, developmental or experimental work, clinical or other programs, and plans for research and development of a GH-VAP Member, and
- (ii) all information conveyed originally orally, provided that original oral conveyance is memorialized in a document (either physical or electronic) delivered within thirty (30) days of the oral conveyance.

Capitalized terms not otherwise defined in this Master CDA shall have the definitions as provided to them in the Guiding Principles.

TERMS AND CONDITIONS OF THIS AGREEMENT

1. The terms and conditions of this Master CDA include the provisions set forth below, as well as the provisions of the Guiding Principles hereto which are incorporated by reference and made a part of this Master CDA. In the event that there are any conflicts between the provisions set forth below and those set forth in the Guiding Principles, the provisions of the Guiding Principles shall control except as otherwise expressly stated in this Master CDA.

2. Each GH-VAP Member (as a **Disclosing Party**) may, at its own discretion, disclose certain Confidential Information owned or rightfully possessed by it to other GH-VAP Members (each as the **Receiving Party**).

3. Each GH-VAP Member, as a Receiving Party, agrees that it will:

- (a) use the Confidential Information received from a Disclosing Party solely for the Purpose,
- (b) treat the Confidential Information with reasonable care to avoid disclosure of the Confidential Information to any third party, person, firm or corporation other than as expressly stated herein, and
- (c) except to the extent prohibited or, where applicable, to the extent authorized by law, be liable for use of the Disclosing Party's Confidential Information outside the scope of the Purpose as well as for any unauthorized disclosure directly resulting from their failure to exercise such reasonable care

4. Notwithstanding anything to the contrary in this Master CDA, the Receiving Party shall have no obligation with respect to the Confidential Information received from a Disclosing Party to the extent such information is:

- (a) already known by the Receiving Party at the time of disclosure as can be demonstrated by competent proof;
- (b) publicly known, or subsequently becomes publicly known, without the wrongful act or breach of this Master CDA by the Receiving Party;
- (c) rightfully received by the Receiving Party from a third party having the lawful right to make such a disclosure, where said disclosure is rightfully made without an express obligation of confidence;
- (d) approved for release or disclosure by written authorization of the Disclosing Party;
- (e) independently developed by the employees or agents of the Receiving Party without the use or knowledge of the Confidential Information provided by the Disclosing Party as can be demonstrated by competent proof; or
- (f) required to be disclosed pursuant to any competent judicial or government request, requirement or order, provided that the Receiving Party so disclosing takes reasonable steps to provide the Disclosing Party with sufficient prior notice in order to allow the Disclosing Party to contest such request, requirement or order and provided that such Confidential

Information is disclosed only subject to reasonably available restrictions on further disclosure and use, and otherwise remains subject to the obligations of confidentiality and restricted use set forth in this Master CDA.

5. Each Receiving Party shall be entitled to disclose the Disclosing Party's Confidential Information to its employees and the employees of its Affiliates as well as its agents and consultants who are bound by confidentiality and restricted use obligations no less strict than those set out herein. However, each Receiving Party shall only disclose the Disclosing Party's Confidential Information to those of its employees, agents, consultants and Affiliates who shall reasonably need to know such Confidential Information in order to evaluate such Confidential Information for the Purpose and/or to make decisions or render advice in connection with the Purpose and who shall be informed of the existence of this Master CDA and shall agree in writing or via employment policy to be bound by the terms hereof or be otherwise bound by law not to disclose such Confidential Information. Each Receiving Party shall be responsible for ensuring that its employees, agents and consultants of its Affiliates, and its consultants who receive Confidential Information comply with the terms of this Master CDA.

6. Subject to exemptions and limitations elsewhere in this Master CDA, the obligations of Paragraph 3 shall remain in effect for each subject disclosure of Confidential Information during the Disclosure Period for a period of three (3) years from date of the termination of the appertaining GH-VAP Projects for which Confidential Information has been transferred.

7. Unless otherwise expressly agreed upon by the Disclosing Party and the Receiving Party, (i) no rights additional to those enumerated in Paragraph 3 in the Confidential Information are provided to any GH-VAP Member under any patent applications, patents, or other proprietary rights of the Disclosing Party and (ii) all Confidential Information is provided on an "AS IS" basis, and all representations and warranties, express or implied, are hereby disclaimed.

8. Except as allowed under Paragraph 4, above, no GH-VAP Member shall be entitled to use the Confidential Information provided by the Disclosing Party for Commercial Purposes without separate written agreement to that effect between the Disclosing Party, the Receiving Party and the Foundation.

9. The Receiving Party agrees to discontinue its use of the Confidential Information and destroy or return to the Disclosing Party all Confidential Information embodied in documents received hereunder upon completion of its use in accordance with this Master CDA or upon request by the Disclosing Party that supplied such Confidential Information (which ever shall occur first); provided, however, one (1) copy of such Confidential Information may be retained by the Receiving Party to preserve an archival record of the same.

10. Any dispute or controversy arising in connection with this Master CDA shall first be referred to the respective officers of the Disclosing and Receiving Parties, or their successors, for attempted resolution in good faith negotiations within thirty (30) days of

notice of such dispute. If such officers are not able to resolve the dispute within the thirty (30)-day period, or any agreed upon extensions, the Disclosing and Receiving Parties shall be free to resolve the dispute through any dispute resolution mechanism they may individually or collectively choose.

11. Except as certain provisions may survive as set forth in Paragraph 12, below, this Master CDA will terminate in its entirety (including but not limited to termination as regards Data transferred under any and all subject Data Transfer Record Forms not previously terminated) upon the termination of the GH-VAP Project of either the Disclosing Party or the Receiving Party or if the Receiving Party is in breach of any of the conditions of this Master CDA.

12. The Definitions and Paragraphs 2-11 and 16 herein, shall survive any termination or expiration of this Master CDA.

13. Per the GH-VAP SOW and upon request of either the Disclosing Party or the Receiving Party, transfer of Material and/or Data may occur and be documented through a research or material transfer agreement.

14. If any provision of this Master CDA is found to be unenforceable, such provision will be limited or deleted to the minimum extent necessary so that the remaining terms remain in full force and effect.

15. No waiver of any term, provision or condition of this Master CDA, whether by conduct or otherwise, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of the same term, provision or condition, or of any other term, provision or condition of this Agreement.

16. No party shall be liable for any failure to perform as required by this Master CDA to the extent such failure to perform is due to circumstances reasonably beyond such party's control, including, without limitation, labor disturbances or labor disputes of any kind, accident, civil disorders or commotions, acts of aggression or terrorism, acts of God, energy or other conservation measures imposed by law or regulation, explosions, failure of utilities, mechanical breakdowns, material shortages, disease, or other such occurrences.

Read and Understood By (Individual Investigator):

Signature: _____

Name: _____

Title: _____

Date Signed: _____