

CAVD DATA & MATERIALS SHARING AGREEMENT

Collaboration for AIDS Vaccine Discovery

in support of

The Global HIV Vaccine Enterprise

THIS AGREEMENT is hereby entered into effective as of December 11, 2006 by and between the parties listed in Annex A (the **Parties**).

WHEREAS, each Party is a member of a Funded Center or Consortium in the Collaboration for AIDS Vaccine Discovery (**CAVD**) - a network of centers and consortia funded by the Bill & Melinda Gates Foundation (the **Foundation**), to support the implementation of the scientific strategic plan of the Global HIV Vaccine Enterprise (the **Enterprise**).

WHEREAS, the Parties include public and private entities, including agencies of sovereign nations and intergovernmental organizations, whose compliance with specific terms of this Agreement may be conditioned by legal limitations.

WHEREAS, the members of each Funded Center or Consortium have entered or will enter into separate agreement(s) among themselves that include a global access strategy and, as appropriate, collaboration agreement and project management committee charter that governs the performance of the corresponding research project funded by the Foundation.

WHEREAS, the CAVD is not a separate legal entity, but is a series of research projects funded by the Foundation in order to create an HIV vaccine discovery collaborative network.

WHEREAS, the agreements needed to establish the CAVD's HIV vaccine discovery collaborative network as a working collaboration will be based on the "Guiding Principles" as set out in Section 2 below.

WHEREAS, the CAVD consists of such centers or consortia (referred to herein, and further defined below, as the **Funded Centers or Consortia**), each of which falls within one of two categories: (i) Vaccine Discovery Consortia (**VDCs**) focusing on the research and development of candidate HIV vaccines designed to stimulate humoral or/and cell-mediated immune responses; and (ii) Central Service Facilities (collectively the **CSFs**) that conduct research and provide services in support of the vaccine discovery goals.

WHEREAS, the CSFs include Vaccine Immune Monitoring Centers (**VIMCs**) which focus on either humoral or cell-mediated immune evaluation; an HIV Specimen Cryorepository (**HSC**); and a Vaccine Immunology Statistical Center (**VISC**).

WHEREAS, it is expected that the Funded Centers or Consortia will work in full collaboration, united by a robust system for the exchange of Data and Materials, and supported, as appropriate, by Alliance Management.

WHEREAS, each of the Parties acknowledge that the primary goals of the CAVD, consistent with those of the Enterprise, are to (i) accelerate the development of an HIV vaccine through the

development and use of innovative technologies and consistent laboratory practices, and (ii) to conduct activities within the CAVD Projects in a manner that is consistent with and in furtherance of the Global Access Objectives.

Now, therefore, the Parties agree to the following terms and conditions:

1. Annex B contains a set of defined terms that have the same definition as used within the documents described in Sections 2-4 below, unless otherwise specifically stated in the particular document.
2. In furtherance of the goals of the CAVD, during the course of performing the CAVD Projects funded by the Foundation, each Party hereby agrees to comply with the Data & Materials Sharing Guiding Principles regarding its sharing of Data and Materials with the other Funded Centers or Consortia and the broader scientific community as set out in Annex C (collectively the **Guiding Principles**).
3. Each Party hereby agrees that Confidential Information exchanged between CAVD Members that are not within the same Funded Center or Consortium shall be exchanged in accordance with the terms of the Master CAVD Confidential Disclosure Agreement set out in Annex D (the **Master CAVD Confidential Disclosure Agreement**).
4. Each Party hereby agrees that (a) Materials generated in the performance of a CAVD Project and (b) Materials generated outside the CAVD Project but transferred for use within a CAVD Project, which are transferred between CAVD Members that are not within the same Funded Center or Consortium shall be transferred in accordance with the terms of the Master CAVD Material Transfer Agreement set out in Annex E (including all attachments thereto the **Master CAVD Material Transfer Agreement**).
5. Each Party hereby agrees that Material that is created or used within activities of the CAVD may be transferred to organizations that are not CAVD Members in accordance with the Master CAVD Material Transfer Agreement set out in Annex E (including all attachments thereto the **Master CAVD Material Transfer Agreement**).
6. All Annexes referenced above and the signatory pages appended below and their respective contents are hereby incorporated into and made a part of this Agreement.

This Agreement may be signed in counterpart, each of which will be considered an original, and all of which collectively will be deemed the same document.

ANNEX A

The list of record for CAVD primary and collaborating institutions is maintained and accessible on the CAVD Portal at https://www.cavd.org/about/Pages/CollaboratingInstitutions_alpha.aspx

ANNEX B

DEFINITIONS

Alliance Manager means the alliance manager established via a contract with the Foundation for the purpose of providing support to the Foundation and the Funded Centers or Consortia with respect to the collective operation of the CAVD, including the implementation of the Data & Material Sharing Agreement and related documents.

CAVD means a network of centers and consortia funded by the Bill & Melinda Gates Foundation, to support the implementation of the scientific strategic plan of the Global HIV Vaccine Enterprise.

CAVD Master CDA means the Master CAVD Confidential Disclosure Agreement as described in Section 3 (and contained in Annex D) of the CAVD Data & Materials Sharing Agreement.

CAVD Master MTA means the Master CAVD Materials Transfer Agreement as described in Section 4 (and contained in Annex E) of the CAVD Data & Materials Sharing Agreement.

CAVD MTA means all of the agreement terms, including the provisions of the CAVD Master MTA, governing the individual transfer of Materials from one CAVD Member to another CAVD Member, each being from different Funded Center or Consortium.

CAVD Invention means any invention, discovery, new use, improvement, or product conceived or first actually reduced to practice as a result of using the Confidential Information, Materials or Data provided by an organization of one Funded Center or Consortium to an organization of another Funded Center or Consortium under the terms of a CAVD CDA or CAVD MTA.

CAVD Member means an institution that is a member of a Funded Center or Consortium and has agreed in writing to this CAVD Data & Materials Sharing Agreement.

CAVD Projects mean the CAVD related research projects being conducted by the Funded Center or Consortia and that are being funded under a grant or contract from the Foundation.

Commercial Purposes means the use of Materials or of Confidential Information by or on behalf of or for research sponsored by (or transfer of Materials or Confidential Information to) a for-profit company. Notwithstanding the foregoing, the CAVD Members acknowledge that to the extent Materials or Confidential Information are used for the CAVD Projects (whether by a for-profit company or otherwise), such use will not be characterized as being conducted for Commercial Purposes.

Confidential Information has the meaning as provided in the Master CAVD Confidential Disclosure Agreement.

Council of CAVD PIs means the council, the members of which will consist of one Principal Investigator from each of the Funded Centers or Consortia, established as a coordinating body for the

purposes to be defined in a charter document to be created by the members in consultation with the Foundation and the Alliance Manager.

CSFs mean the Funded Centers or Consortia that are the Central Service Facilities within the CAVD, which conduct research and provide services in support of the vaccine discovery goals and that include but are not limited to:

The Vaccine Immune Monitoring Centers (**VIMCs**), which focus on either humoral or cell-mediated immune evaluation;

An HIV Specimen Cryorepository (**HSC**); and

A Vaccine Immunology Statistical Center (**VISC**).

Data means recorded information used or generated in the performance of a CAVD Project.

Funded Center or Consortium means a specific organization or group of organizations that is participating in the CAVD in conducting a particular project that is being funded under a grant or contract from the Foundation. When described as taking any action (including, without limitation, receiving notices or providing permissions), a Funded Center or Consortium will take such action through the CAVD Project's Principal Investigator, unless the CAVD Members within the Funded Center or Consortia decide otherwise (with notice of such decision to be provided to the Foundation and the Alliance Manager). All Funded Centers or Consortia (and its respective CAVD Members) shall be listed on Annex A, which shall be updated by the Alliance Manager (and distributed to the Foundation and all then existing Funded Center or Consortium) as soon as possible upon a group commencing or ceasing its participation in the CAVD.

Global Access Objectives means (i) the prompt dissemination of new scientific information within the CAVD, across the Enterprise, and with the broader scientific community and (ii) facilitating the accessibility of future HIV vaccines to people most in need within developing countries.

Global HIV Vaccine Enterprise means an alliance of independent organizations around the world dedicated to accelerating the development of a preventive HIV vaccine by (i) implementing a shared strategic plan for HIV vaccine research that spans vaccine discovery, product development and manufacturing, and clinical trials, (ii) mobilizing significant new funding to achieve the scientific plan, and (iii) promoting more efficient, faster ways for researchers to share successes and failures and avoid duplication of efforts, and as further described at www.hivvaccineenterprise.org.

Materials – includes, but is not limited to, reagents, immunogens, vaccine products, adjuvants, viral isolates, DNA, RNA, vectors, plasmids, peptides, antibodies, hybridomas, monoclonal antibodies, peripheral blood mononuclear cells, sera, Progeny, and Unmodified Derivatives, or other preclinical and clinical samples. For purposes of this definition:

Progeny means unmodified descendants from the original Materials (as described in the specific CAVD MTA document being used to transfer the Materials), such as virus from virus, cell from cell, or organism from organism.

Unmodified Derivatives means substances created by the recipient of the Materials which constitute an unmodified functional subunit or product expressed by the original Materials (as described in the specific CAVD MTA being used to transfer the Materials). Some examples include (but are not limited to) subclones of unmodified cell lines, purified or fractionated subsets of the original Material, proteins expressed by DNA/RNA supplied by the provider of the Materials, or monoclonal antibodies secreted by a hybridoma cell line.

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**).

VDCs means the Funded Centers or Consortia that are the Vaccine Discovery Consortia within the CAVD, which focus on the research and development of HIV candidate vaccines designed to stimulate humoral or/and cell-mediated immune responses.

ANNEX C

DATA & MATERIALS SHARING GUIDING PRINCIPLES

Collaboration for AIDS Vaccine Discovery
in support of
The Global HIV Vaccine Enterprise

1. DATA SHARING PRINCIPLES

a. Definitions

For purposes of these Guiding Principles:

- i. **Non-Standardized Data** means all Data not resulting from Standardized Assays other than Comparative Data.
- ii. **Standardized Data** means all Data resulting from an assay after it has been defined as a Standardized Assay; provided, however, to generate Standardized Data, the Standardized Assay must be performed by a person or organization that is certified to perform the Standardized Assay as determined by the Council of CAVD PIs.
- iii. **Standardized Assays** mean a limited number of assays to be defined by the Council of CAVD PIs, in discussions with the Alliance Manager and the Foundation, as described in Section 1.e. below.
- iv. **Comparative Data** means all Data resulting from comparative evaluation of Non-Standardized Data or Standardized Data produced by a CAVD Member.
- v. **Comparative Standardized Data** means all Data resulting from comparative evaluation of Standardized Data produced by a CAVD Member; accordingly Comparative Standardized Data is a subset of the Comparative Data.

Capitalized terms not otherwise defined in these Guiding Principles shall have the definitions as provided to them in Annex B to the CAVD Data & Materials Sharing Agreement.

b. Inventions

- i. With respect to CAVD Inventions for which a patent is sought, inventorship will be determined by the law governing the jurisdiction in which the patent application is filed.
- ii. Ownership of CAVD Inventions is outside the scope of these Guiding Principles and should be addressed by the CAVD Members concerned under a separate contractual arrangement.
- iii. To the extent not prohibited by law, regulation or third-party obligation (which obligation exists prior to the organization becoming a CAVD Member), each CAVD Member agrees to grant to the other CAVD Members upon request a fully

paid-up, non-exclusive, royalty free right-to-use all CAVD Inventions for purposes of education, as well as research, within a Funded Center or Consortium in support of the development of an HIV vaccine. To the extent such prospective grants by a CAVD Member are prohibited by law, regulation, or pre-existing third-party obligation, the relevant CAVD Member will in good faith seriously consider requests from CAVD Members for the right to use such CAVD Inventions for such purposes and explore ways to enable such use on similar terms. The grant of the right to use provided under this paragraph does not waive any obligations under the CAVD Master CDA, the CAVD Master MTA, or other contractual arrangement between the CAVD Members.

c. Management of Data

- i. Management of Data generated within a single VDC will be determined by the terms of the agreements that govern that VDC.
- ii. The ownership of Data is outside the scope of these Guiding Principles and should be addressed by the CAVD Members under a separate contractual arrangement.
- iii. No CSF shall assert against any CAVD Member any database rights, copyrights, moral rights or other rights in the Data incorporated into any database by a CSF in support of the CAVD. The CAVD Member that submitted Data (or Materials used to generate the Data) to the CSF shall not assert against any CAVD Members any database rights, copyrights, or moral rights to such Data incorporated into a database by a CSF in support of the CAVD.

d. Confidentiality of Information

Subject to the provisions contained in these Guiding Principles, Confidential Information (as defined in the CAVD Master CDA), including but not limited to Data, that is shared between CAVD Members of different Funded Centers or Consortia will be held in confidence according to the terms of a CAVD Master CDA.

e. Treatment of Data

- i. The Council of CAVD PIs will work with the Alliance Manager and the Foundation to:
 1. Approve the applicable VIMC's general process by which the VIMC exploratory assays generating Non-Standardized Data may be redefined by the VIMC as Standardized Assays.
 2. Determine the process by which Data will be physically or electronically transferred among the Funded Centers or Consortia.
 3. Identify the position of the individual within each VDC who shall be the primary contact person responsible for coordinating submission and receipt of Data and/or Materials to the CSFs on behalf of such VDC and its members.

- ii. All Funded Centers or Consortia will work together with the VISC and, when required, the Alliance Manager and the Foundation, to establish statistical plans and data standards for each CAVD Project for which Data is to be submitted to a CSF, including the VISC, in accordance with applicable laws and regulations including (but not limited to) those related to data privacy and security. Prior to the initiation of any laboratory or statistical study by the VIMCs or VISC, the VDC will work with the VIMC or VISC, as appropriate, to register the study with the VISC. VDCs acknowledge the importance of consulting with the VISC regarding study design, as well as Data organization and delivery, in order to facilitate the establishment of data standards and subsequent statistical analyses.
- iii. With respect to all Non-Standardized Data generated by a CSF in the evaluation of a candidate vaccine, or components of a candidate vaccine:
 - 1. All Non-Standardized Data generated on behalf of a VDC will be transferred to the applicable VDC within twenty (20) days following the production of the Non-Standardized Data.
 - 2. The applicable VDC will have discretion regarding whether and when Non-Standardized Data (that is to be transferred to it according to the above paragraph 1) will be submitted to the VISC.
- iv. With respect to all Non-Standardized Data generated by a VDC in the evaluation of a candidate vaccine, or components of a candidate vaccine, the VDC will have discretion regarding whether and when such Non-Standardized Data will be submitted to the VISC.
- v. With respect to all Standardized Data and Comparative Standardized Data generated by or for a Funded Center or Consortium in the evaluation of a candidate HIV vaccine, or components of a candidate vaccine (collectively, solely for purposes of the following paragraphs of this clause v., **Section e.v Data**): All Section e.v Data generated by or on behalf of a Funded Center or Consortium (unless generated by the VISC) will be transferred to the VISC within thirty (30) days from the completion of the final analysis. The Funded Center or Consortium that generated the Section e.v Data will notify any other Funded Center or Consortia whose CAVD Member(s) provided the underlying Material or Data used to generate the Section e.v Data when such Section e.v. Data has been transferred to the VISC.
 - 1. All Section e.v Data that is held or generated by the VISC will be transferred initially only to the Funded Center or Consortium whose member(s) provided the underlying Materials or Data used to generate the Section e.v Data. Such transfer of the Section e.v Data will be near real-time for rapid access by the applicable Funded Center or Consortium or at least within seven (7) days of generation by the VISC.
 - 2. The Funded Center or Consortium that provided the underlying Material or Data used to generate the Section e.v Data will then have an exclusive review period of thirty (30) days from the date it receives the Section e.v Data.

3. Unless all of the applicable Funded Centers or Consortia provide their written permission sooner, at the end of that exclusive review period all of the Section e.v Data will be disclosed to all of the other Funded Centers or Consortia by a mechanism established by the Alliance Manager with the Council of CAVD PIs and the Foundation. However, any member of the applicable Funded Center or Consortium shall be entitled to demand, via written notice submitted to the Alliance Manager before the end of such exclusive review period, that such disclosure be delayed for an additional sixty (60) days if necessary to evaluate whether to seek intellectual property protection of an invention that is disclosed in whole or in part by the Section e.v Data.
4. Upon disclosure to the other Funded Centers or Consortia in accordance with paragraph 3 above, the CAVD Members agree to maintain the Section e.v Data among themselves in confidence for a period of ninety (90) days after receipt, unless a longer period is otherwise established by the Council of CAVD PIs to enable the relevant Funded Centers or Consortia sufficient time to prepare such Section e.v Data for Publication; provided, however, following the foregoing described ninety (90) day period, notwithstanding the Council of CAVD PIs, the CAVD Members will be entitled to use such Section e.v Data for the purpose of seeking additional grant or other research funding, although there may be a potential that the funding application might be Published. The Funded Center or Consortia whose member(s) provided the Material and/or Data used to generate the Section e.v Data will then make reasonable efforts to disseminate such Section e.v Data to the broader scientific community.
5. When Section e.v Data is Published or otherwise publicly disseminated outside the Funded Centers or Consortia, the entity with which the Section e.v Data is shared will be required to acknowledge, in any of its subsequent Publications which use the Section e.v Data, that the Section e.v Data was generated through the activities of a CAVD Project.
6. When Section e.v Data is shared under an obligation of confidentiality outside the Funded Centers or Consortia, the entity with which the Section e.v Data is shared will be required to acknowledge, in writing, that the Section e.v Data was generated through the activities of a CAVD Project and will themselves adhere to the Global Access Objectives with respect to its use of the Section e.v Data and any invention arising out of the use of such Section e.v Data.

f. Publication Rights

Subject to the provisions of Section 1.e, Data will be Published according to the following principles:

- i. For Non-Standardized Data and Standardized Data generated by a CSF on behalf of a VDC or VDCs, the individual CAVD Member(s) of the VDC that provided the Material used to generate such Data may Publish on that Data accompanied by the appropriate attributions (co-authorship or acknowledgement as appropriate, in

accordance with authorship guidelines referenced below where Publication is in written form) of the relevant Funded Centers or Consortia that contributed to the generation of the Data. The individual CAVD Member(s) of the CSF that generate Non-Standardized Data and Standardized Data may also Publish on such Data with the prior consent (not to be unreasonably withheld) and accompanied by the appropriate attribution (co-authorship or acknowledgement as appropriate, in accordance with the authorship guidelines referenced below) of the individual CAVD member(s) of the VDC that provided the Material used to generate the Data. In this case, the CSF shall furnish the applicable CAVD Member(s) with a copy of any proposed Publication for review and comment at least thirty (30) days prior to submission for publication and shall reasonably consider any comments provided.

- ii. For Comparative Data, the Funded Centers or Consortia whose CAVD Member(s) generated portions of the Data or that contributed to the comparative study will have the joint right to Publish on such Comparative Data. In this case, the CAVD Member that intends to Publish shall furnish the other applicable CAVD Member(s) with a copy of any proposed Publication for review and comment at least thirty (30) days prior to submission for publication and shall reasonably consider any comments provided and ensure that the Publication of the Comparative Data is accompanied by the appropriate attributions (co-authorship or acknowledgement as appropriate, in accordance with the authorship guidelines referenced below) for each of the applicable Funded Centers or Consortia. In the event the Publication will be a meeting presentation, the foregoing described thirty (30) day review period shall not apply; provided, however, the publishing Party shall obtain consent of the others prior to such Publication.
- iii. Authorship guidelines will be in accordance with those of the International Committee of Medical Journal Editors, or other generally recognized standards.

2. MATERIALS SHARING PRINCIPLES

- a.** The CAVD Members acknowledge that they are strongly encouraged to share Materials among themselves, but are under no obligation to do so. The CAVD Members also acknowledge that their ability to share Materials may be limited for various reasons, including the availability of the Materials. The CAVD MTA shall define the terms, including the authorized use, of (i) the transfer of Materials generated in the performance of a CAVD Project and (ii) the transfer of Materials generated outside the CAVD Project but which are transferred for use within a CAVD Project.
- b.** Ownership of Materials is outside the scope of these Guiding Principles and should be addressed by the CAVD Members under the relevant Material Transfer Record Form in the form attached to the CAVD Master MTA.
- c.** Materials must be collected, maintained and used in accordance with the necessary informed consent and regulatory approval (if applicable) in support of these Guiding Principles.
- d.** Consistent with the strong encouragement of sharing, CAVD Members shall use good faith efforts to submit Materials that emanate from their evaluation (or an evaluation on

their behalf) of a candidate HIV vaccine, or components of a candidate HIV vaccine, for comparative evaluation using Standardized Assays.

- e. Where Materials that are generated from the activities of a CAVD Project are shared outside the CAVD Members, the non-CAVD Member entity with which the Materials are shared will be required to acknowledge, in writing, that the Materials were generated through the use of Foundation funding and such entity shall agree to adhere to the Global Access Objectives with respect to its use of the Material and any improvement, modification or invention in such Material.
- f. With respect to the HSC:
 - i. The CAVD Members are strongly encouraged to deposit Materials with the HSC;
 - ii. Within the framework of the CAVD Master MTA, the HSC will develop mechanisms to share Materials among the CAVD Members and the broader scientific community with the permission of the Funded Center or Consortium whose member(s) provided the original Materials; and
 - iii. If the organization that is serving in the role of HSC does not continue in that role or ceases to be a Funded Center or Consortium, the Council of CAVD PIs, in consultation with the Alliance Manager and the Foundation, will make a recommendation regarding the disposition of Materials deposited with that organization, including possible transfer to another CSF or to another organization that can fulfill role of HSC.
- g. The Funded Centers or Consortia will, on a semi-annual basis, provide a list of relevant Materials that are potentially available for use by the CAVD Members. The Council of CAVD PIs will, in consultation with the Alliance Manager and the Foundation, establish the mechanism for creating and updating a consolidated list of such Materials.

3. UNIQUENESS OF IDENTIFIERS

For bookkeeping purposes in order to ensure that Data and Materials generated or provided may be associated with the source CAVD Center or Consortium, all Funded Centers or Consortia will comply with an identification naming convention that will be used across the CAVD which will be established by the Council of CAVD PIs in consultation with the Alliance Manager and the Foundation; such identifiers shall be subject to the considerations identified in Section 1.e. Unique identifiers will be used to identify (consistent with applicable privacy laws and regulations) all CAVD Members, investigators within the CAVD Members, Material, documents, and Data, as well as transfers of Materials, documents and Data between CAVD Members.

ANNEX D

MASTER CAVD CONFIDENTIAL DISCLOSURE AGREEMENT

WHEREAS, the scope and nature of confidentiality obligations with respect to information, including data, that is transferred among CAVD Members within the same Funded Center or Consortium is outside the scope of this Master CDA and shall be determined in accordance with the separate agreements entered into among themselves that include a global access strategy and, as appropriate, collaboration agreement and project management committee charter that governs the performance of the corresponding research project funded by the Foundation.

WHEREAS, the CAVD Members anticipate that any exchange of Non-Standardized Data, Standardized Data, Comparative Data and Comparative Standardized Data, along with other forms of information (including, without limitation, information concerning Materials) between CAVD Members of different Funded Centers or Consortia will be in accordance with the terms of this Master CDA.

WHEREAS, the CAVD 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 **CAVD Projects** (the "**Purpose**").

Now, therefore, the CAVD Members agree to the following terms and conditions with respect to the transfer of Confidential Information between CAVD Members of different Funded Centers or Consortia:

DEFINITIONS

Affiliate means any business entity controlled by, controlling or under common control of a CAVD 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 provided at any CAVD-Related Meeting with respect to any aspect of a CAVD Project, regardless of whether or not such information is identified or marked as confidential and regardless of whether or not a written record is subsequently provided if the information was provided orally and (ii) all recorded information, including data marked "Confidential" or bearing a similar legend.

CAVD-Related Meeting means any meeting or discussion (whether in person, by written exchange (including, without limitation, emails, by telephone or video conference calls, or otherwise) among or on behalf of multiple CAVD Members that are associated with more than one Funded Center or Consortia.

Capitalized terms not otherwise defined in this Master CDA shall have the definitions as provided to them in Annex B to the CAVD Data & Materials Sharing Agreement.

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 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 CAVD Member (as a **Disclosing Party**) may, at its own discretion, disclose certain Confidential Information owned or rightfully possessed by it to other CAVD Members from different Funded Centers or Consortia (each as the **Receiving Party**).
3. The CAVD Members shall ensure that all participants under their control in a CAVD-Related Meeting will have executed an agreement obligating them to refrain from disclosure or use of Confidential Information in any manner inconsistent with this CAVD Master CDA.
4. Each CAVD 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
5. 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.

6. Each Receiving Party shall be entitled to disclose the Disclosing Party's Confidential Information to its employees and the employees of its Affiliates (as defined below) 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.

7. Notwithstanding the provisions of Paragraphs 4 and 6 above, the transfer, disclosure, use, dissemination, and publication of Section e.v Data (as that term is defined in Section e.v of the Guiding Principles) will be governed by Section e.v of the Guiding Principles.

8. Subject to exemptions and limitations elsewhere in this Master CDA, the obligations of Paragraph 4 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 CAVD Projects for which Confidential Information has been transferred.

9. Unless otherwise expressly agreed upon by the Disclosing Party and the Receiving Party, no rights additional to those enumerated in Paragraph 4 in the Confidential Information are provided to any CAVD Member under any patent applications, patents, or other proprietary rights of the Disclosing Party. Except as allowed under Paragraph 5, above, No CAVD Member shall be entitled to use the Confidential Information provided by the Disclosing Party for Commercial Purposes without separate written agreement to that effect.

10. The Receiving Party agrees to discontinue its use of the Confidential Information and destroy or return to the Disclosing Party all written Confidential Information received hereunder or Confidential Information that has been reduced to a written form 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.

11. 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.

12. Except as certain provisions may survive as set forth in Paragraph 13, 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 CAVD 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.

13. The Definitions and Paragraphs 2, 3, 7, 8, 9, 10, 11, 12, and 13 herein, and the CAVD Data & Materials Sharing Agreement, shall survive any termination or expiration of this Master CDA.

14. Upon request of either the Disclosing Party or the Receiving Party, transfer of Data may be documented through a Data Transfer Record Form (in the form as contained in **Attachment A**) to be completed by the Disclosing and the Receiving Party. Data Transfer Record Form shall not be used for transfer of Section e.v Data, which shall exclusively be governed by the provisions of Section 7 of this Master CDA.

15. 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.

16. 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.

17. 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.

**ATTACHMENT A
DATA TRANSFER RECORD FORM**

DISCLOSING PARTY (*Institution/Company name*):

DISCLOSING PARTY SCIENTIST:

RECEIVING PARTY (*Institution/Company name*):

RECEIVING PARTY SCIENTIST:

Description of the DATA: *Exhibit I (attached)*

The ORIGINAL DATA(S) described in Exhibit I (attached) is / are supplied by DISCLOSING PARTY to the RECEIVING PARTY subject to the terms and conditions of the MASTER CDA.

DISCLOSING PARTY hereby gives its authorization for the RECEIVING PARTY to further transfer the DATA to other CAVD Members in accordance with the terms of the Master CDA. The DISCLOSING PARTY gives such authorization by initialing here: _____

-or-

DISCLOSING PARTY hereby withholds its authorization for the RECEIVING PARTY to further transfer the DATA to other CAVD Members in accordance with the terms of the Master CDA. The DISCLOSING PARTY withholds such authorization by initialing here: _____

Description of the intended and authorized use of the DATA: _____

(Use additional pages if required)

The following are the terms and conditions of the allocation of ownership/licensing of Data and CAVD Inventions and other inventions that arise from use of the Data. This Disclosing and Receiving Party recognize that these terms and conditions must take into account and be consistent with the objectives and intentions of the Guiding Principles and the Global Access Objectives.:

(Use additional pages if required)

[Optional clause] Any dispute or controversy arising in connection with the transfer of Data documented herewith which is not resolved by the designated officers of this Disclosing and Receiving Party in accordance with the Master CDA shall be finally settled in accordance with the following terms:

DISCLOSING PARTY

RECEIVING PARTY

By: _____
Name:
Title:
Date: _____

By: _____
Name:
Title:
Date: _____

Read and Understood :

By: _____
Name:

By: _____
Name:

DISCLOSING PARTY SCIENTIST

RECEIVING PARTY SCIENTIST

EXHIBIT I

ORIGINAL DATA(S)

List the type of Data to be transferred and, if applicable, identify the software (and version) used to compile or organize the data.

ANNEX E

MASTER CAVD MATERIAL TRANSFER AGREEMENT

WHEREAS, consistent with Section 4 of the CAVD Data & Materials Sharing Agreement, the terms of this Master MTA shall govern the transfers of Materials from and between the Funded Centers or Consortia in connection with activities carried out under the CAVD.¹ The CAVD Members recognize that two sets of additional standard MTA provisions are available for use with this Master MTA: (i) one for use in the transfer of Materials by CAVD Members to the HSC, which is attached hereto as **Attachment A.1** and (ii) one for use in the transfer of Material that is created or used within activities of the CAVD but is to be transferred to organizations that are not CAVD Members, which is attached hereto as **Attachment A.2**.

Now, therefore, the CAVD Members agree to the following terms and conditions with respect to the transfer of Materials between CAVD Members of different Funded Centers or Consortia.

DEFINITIONS: All capitalized terms not otherwise defined in this Master MTA shall have the definitions as provided to them in Annex B to the CAVD Data & Materials Sharing Agreement.

Provider means the entity that is providing the Materials and / or having the Materials provided by another entity on its behalf, including the principal investigator and / or co-principal investigator or his/her designee employed by such entity who will be physically supplying the Materials.

Recipient means the entity that is receiving the Materials, including the principal investigator or, where applicable, co-principal investigator or his/her designee employed by such entity who will be physically receiving the Materials.

TERMS AND CONDITIONS OF THIS AGREEMENT:

1. The terms and conditions of this Master MTA include the provisions set forth below, as well as the provisions of the Guiding Principles which are incorporated by reference and made a part of this Master MTA. 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 MTA.

2. Transfer of all Materials by CAVD Members under this Master MTA shall be documented through the completion of the Material Transfer Record Forms (in the form as contained in **Attachment B**), a copy of which will be provided by the Provider to the Alliance Manager for each Material transfer. Upon each Material Transfer Record Form, the Provider shall, among other things, describe the Material and set forth the additional terms and conditions of the use and the transfer of the Materials.

¹ Material transfers among members or collaborators of a single Funded Center or Consortium are regulated by the provisions of internal collaboration agreements or material transfer agreements, although each Funded Center or Consortium may elect to have this Master MTA govern Material transfers between their own collaborators.

3. The Recipient agrees that Materials (a) will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects unless such use is expressly approved by the Provider in writing and the Recipient's use shall be in accordance with the appertaining clinical protocol, informed consent and subject to any required Institutional Review Board and / or Ethics Committee approvals and / or other necessary approvals as applicable; (b) will not be used for Commercial Purposes; and (c) will only be used by individuals who are legally obligated, in the manner and to the extent required in the applicable Material Transfer Record Forms, to allocate their respective right in any and all CAVD Inventions (and any patent rights or other rights arising therefrom); and (d) will not be given or made available to CAVD Members or third parties unless approval to do so has been given on the respective Material Transfer Record Form by the Provider and in which case such transfer will also be under the conditions of this Master MTA, and subject to the approval of the originator of the materials.

4. It is acknowledged that the results of the research using the Materials may be important to the Provider in its attempts to attract good researchers and secure research funding for HIV vaccine-related or other research. Such recognition may be primarily established by reference to the use of Materials by third parties, such as the Recipient, in Publications. It is further acknowledged that the failure to obtain such recognition may adversely affect the Provider's ongoing research activities and funding. Accordingly, the Recipient hereby agrees that it will notify the Provider and, at least 30 days prior to submission, provide a copy of any Publication concerning the research in which such Materials were utilized to the Provider. The Recipient shall reasonably consider any comments the Provider offers and will make appropriate attributions (co-authorship or acknowledgement) in all such Publications where the Provider's Materials were used in the Recipient's research.

5. (a) It is understood and agreed that the attachments to this Master MTA, and the CAVD Data & Materials Sharing Agreement, set forth certain other provisions regarding confidentiality, the sharing of research results, CAVD Inventions, the scientific and charitable goals of the CAVD Projects, and other related issues and appertaining activities under this Master MTA.

(b) The use and allocation of ownership or licensing, if any, of the Materials and CAVD Inventions arising through the use of the Materials is addressed in the applicable Material Transfer Record Forms. Such ownership or licensing provisions shall survive termination of the Master MTA and shall apply to further transfers of the Material by the Recipient as applicable.

6. Any Materials transferred pursuant to this Master MTA are understood to be experimental in nature and may have hazardous properties. **THE PROVIDER MAKES NO REPRESENTATIONS NOR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIALS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER THIRD PARTY PROPRIETARY RIGHTS, OR THAT THE MATERIALS WILL NOT POSE A HEALTH OR SAFETY RISK.**

7. The Materials are supplied without cost to CAVD Members but, unless provided for otherwise, the Recipient shall reimburse Provider for any reasonable shipping and related costs that may be incurred when preparing and sending the Materials to the Recipient. The Recipient and recipient scientist shall use the Materials in accordance with good laboratory practice and the highest standards of skill and care and shall ensure compliance with any applicable laws and regulations governing the transportation, keeping or use of the Materials.

8. Except to the extent prohibited or, where applicable, to the extent authorized by law, Recipient assumes all liability for claims for damages that may arise from its use, storage, and/or disposal of the Materials for activities carried out pursuant to this Agreement. The Provider will not be liable to the Recipient for any loss, claim, or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from the use, storage, and/or disposal of the Materials by the Recipient, except to the extent permitted by applicable law when such loss, claim, or demand is caused by the gross negligence and/or willful misconduct of the Provider. All Materials will be shipped EXW² Provider's place of business for activities carried out pursuant to this Agreement (unless Provider and Recipient mutually agree to a different Incoterm shipping classification).

9. Provider certifies that, if applicable to the Material being supplied under this Master MTA, it has obtained all informed consent(s) and / or other necessary approval(s) and / or authorization(s) in the collection of the Materials necessary to provide the Materials for use in accordance with the respective Material Transfer Record Form. Recipient agrees to handle, store, and use the Materials in a safe manner and in compliance with all applicable statutes and regulations, including applicable governmental regulations and guidelines as well as the requirements of national drug regulatory authorities and other relevant regulatory agencies. Recipient certifies that it has obtained any Institutional Review Board and / or Ethics Committee and / or other approvals that may be required for the use of Materials received under this Master MTA as outlined in the respective Material Transfer Record Form.

10. This Master MTA will terminate as regards only Materials transferred under a subject Material Transfer Record Form on the earliest of the following dates: (a) on completion of the Recipient's use of the Materials for the CAVD Projects; or (b) on termination of the appertaining CAVD Projects for which Materials were transferred. Upon such termination Recipient will immediately discontinue its use of the Materials and will, upon direction of the Provider, return or destroy any remaining Materials. Recipient will also require third parties to which it has provided the Material to discontinue their use of the Materials and return or destroy any remaining Materials. Termination of the Provider's CAVD Project shall not affect the Provider's rights hereunder.

11. Except as certain provisions may survive as set forth in Paragraph 12 below, this Master MTA will terminate in its entirety (including but not limited to termination as regards Materials transferred under any and all subject Material Transfer Record Forms not previously terminated) upon the termination of the CAVD Project of either the Provider or the Recipient.

12. The Definitions and Paragraphs 1, 3, 4, 5, 6, 7, 8 9, 10, 11, 12 and 13 herein, the CAVD Data & Materials Sharing Agreement, and the rights of any Provider set forth herein shall survive any termination or expiration of this Master MTA, including but not limited to subject termination as regards Materials transferred under a subject Material Transfer Record Form.

13. Any dispute or controversy arising in connection with this Master MTA shall first be referred to the parties' respective officers that signed this document, on behalf of the Recipient and Provider, 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

² EXW is an Incoterm abbreviation for "EX Works." Ex works means that the Provider delivers when he places the goods at the disposal of the Recipient at the Provider's premises or another named place (i.e. works, factory, warehouse, etc.) not cleared for export and not loaded on any collecting vehicle. This term thus represents the minimum obligation for the Provider, and the Recipient has to bear all costs and risks involved in taking the goods from the Provider's premises.

any agreed upon extensions, the Recipient and Provider shall be free to resolve the dispute through any dispute resolution mechanism they may individually or collectively choose.

14. If any provision of the Agreement 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 the Agreement, 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 the Agreement 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.

ATTACHMENT A.1

Additional provisions to be included when transferring Materials from a CAVD Member to the HSC:

1. In transferring Materials to the HSC, the Provider may acknowledge and give the HSC authority to further distribute those Materials to CAVD Members for the purposes of conducting research in connection with the CAVD Projects under provisions of the Master MTA. The HSC will give Provider prompt advanced written notice of any such distribution, including the identity of the recipient and the date of distribution.

The Provider gives the HSC such authority by initialing here: _____

The Provider withholds from the HSC such authority by initialing here: _____

2. Following the expiration or termination of the CAVD Project for which Materials were provided to the HSC, any Materials remaining in the HSC may, at the discretion of the HSC, be retained by the HSC or transferred to other CSFs unless otherwise notified in writing by the Provider at the time such Materials were provided to the HSC that it would wish the HSC to take alternate action.

The Provider hereby instructs the HSC to take the following alternate action with respect to the Materials following the expiration or termination of the CAVD Project:

_____ *(Add additional pages if required)*

3. The HSC shall share Materials with parties that are not CAVD Members (in particular the broader scientific community), only with the permission of the Provider. The HSC will give Provider prompt advanced written notice of any such distribution, including the identity of the recipient and the date of distribution.

The Provider gives the HSC such permission by initialing here: _____

4. In the event the HSC transfers Materials to third parties, such transfers will be governed by the terms of the Master MTA and the additional provisions in Attachment A.2.

ATTACHMENT A.2

[This attachment includes additional provisions that must be included in a Material Transfer Agreement when transferring Materials that are created or used within activities of the CAVD to Recipients that are not CAVD Members.]

1. The Recipient acknowledges that the Materials were generated through the use of funding by the Bill & Melinda Gates Foundation.
2. The Recipient will adhere to the global access objectives of (i) the broad and prompt dissemination of research information generated through use of the Materials to the scientific community and (ii) the development of an HIV vaccine through use of the Materials that will be made accessible to the people most in need in the developing world in its use of the Materials and any improvements, modifications or inventions that may arise through such use.
3. The Recipient will require any person or entity to whom or which it provides the Materials and any improvements, modifications or inventions that have arisen through the Recipient's use of the Materials to include the global access objectives stated above in paragraph 2 in connection with agreements through which it provides the Materials or permission or licenses to use such improvements, modifications or inventions.

**ATTACHMENT B
MATERIAL TRANSFER RECORD FORM**

PROVIDER (*Institution/Company name*):

PROVIDER Contact:

Note: If PROVIDER is NOT the original PROVIDER of any of the MATERIALS, then identify the ORIGINAL PROVIDER(S) below and in the descriptions listed in Exhibit I.

ORIGINAL PROVIDER(S) (*Institution/Company name*):

RECIPIENT (*Institution/Company name*):

RECIPIENT Contact:

Description of the MATERIAL: *Exhibit I (attached)*

The ORIGINAL MATERIAL(S) described in Exhibit I (attached) is / are supplied by PROVIDER to the RECIPIENT subject to the terms and conditions of the MASTER MTA.

PROVIDER hereby gives its authorization for the Recipient to further transfer the MATERIAL to other CAVD Members in accordance with the terms of the Master MTA (including the Attachment A.2 thereto). The original Provider will be notified by the Provider of each subsequent transfer of Materials. The Provider gives such authorization by initialing here: _____

-or-

PROVIDER hereby withholds its authorization for the Recipient to further transfer the MATERIAL to other CAVD Members in accordance with the terms of the Master MTA (including the Attachment A.2 thereto). The Provider withholds such authorization by initialing here: _____

Description of the intended and authorized use of the MATERIALS: _____

(Use additional pages if required)

Describe any special handling or storage instructions for the MATERIALS: _____

(Use additional pages if required)

The following are the terms and conditions of the use, transfer, allocation of ownership/licensing of Materials and CAVD Inventions and other inventions that arise from use of the Materials. This Provider and Recipient recognize that these terms and conditions must take into account and be consistent with the objectives and intentions of the Guiding Principles and the Global Access Objectives:

(Use additional pages if required)

[Optional clause] Any dispute or controversy arising in connection with the transfer of Materials documented herewith which is not resolved by the designated officers of this Provider and Recipient in accordance with the Master MTA shall be finally settled in accordance with the following terms:

By signing the RECIPIENT accepts all terms and conditions expressly sated in this Attachment B and/or Exhibit I.

PROVIDER

RECIPIENT

By: _____
Name: _____
Title: _____
Date: _____

By: _____
Name: _____
Title: _____
Date: _____

Duplicate originals of this form shall be fully completed and executed with the Recipient being notified by the Provider of the upcoming transfer via a copy of the completed subject Material Transfer Record Form (supplied electronically via facsimile transmission, pdf attachment to e-mail, or the like) within seventy-two (72) hours of the Provider’s completion and execution of this Material Transfer Record Form and a copy being supplied electronically (via facsimile transmission, pdf attachment to e-mail, or the like) to _____ and / or facsimile number _____ or to such other e-mail address and/ or facsimile number as may be provided by the management and operations group of the in the future) by the Provider within seventy-two (72) hours of its completion and execution of this Material Transfer Record Form.

EXHIBIT I

ORIGINAL MATERIAL(S)

Describe the Material being transferred under this Master MTA (e.g. reagents, immunogens, vaccine products, adjuvants, hybridomas, monoclonal antibodies, peripheral blood mononuclear cells, sera, or other preclinical and clinical samples generated in the course of vaccine research and development studies supported by the CAVD) as well as the unique barcode identifier or other unique identifier. In addition, if Provider is NOT the original Provider of any of the Materials, identify the original Provider of each Material also.

SIGNATORY
to the
CAVD DATA & MATERIALS SHARING AGREEMENT

IN WITNESS HEREOF, the undersigned Party hereby executes the CAVD Data & Materials Sharing Agreement (DMSA), which includes agreement to adhere to the Data & Materials Sharing Guiding Principles (Annex C), and to be bound by the terms of the Master CAVD Confidential Disclosure Agreement and Master Materials Transfer Agreement (Annexes D and E, respectively).

Institutional Signatory

Institution:

Signature:

Name:

Title

Date Signed

Signature:

Name:

Title

Date Signed

Investigator Acknowledgement

Signature:

Name:

Date Signed