Global Health Discovery Collaboratory
Guiding Principles

THESE GLOBAL HEALTH DISCOVERY COLLABORATORY GUIDING PRINCIPLES (these "**Principles**") (1) amend and restate the Global Health Vaccine Accelerator Program ("**GH-VAP**") Data Sharing Guiding Principles, a.k.a. the GH-VAP Data Sharing and Principles Agreement (the "**DSPA**"), and (2) set forth certain terms and conditions applicable to each Party's participation as a member of the Global Health Discovery Collaboratory (the "**Collaboratory**"). A person will be considered a "**Party**" to these Principles, and the terms and conditions of these Principles will be binding on such person, on the date such person executes these Principles (all such persons, collectively, the "**Parties**"). The individual who accepts these Principles represents that he or she is authorized to enter into these Principles on behalf of the Party. Each Party hereby agrees to the below terms and conditions.

1. **Collaboratory Purpose**.

(a) Each Party is a member of the **Collaboratory** and it or its Affiliate has received (or will receive) funding from the Bill & Melinda Gates Foundation (the "**Foundation**") to support its project(s) in furtherance of the Global Access Objectives (each such project, a "**Project**") pursuant to one or more grant agreements with the Foundation (each such agreement, a "**Grant Agreement**").

(b) The purpose of the Collaboratory is to accelerate achievement of the Global Access Objectives by:

(i) Creating a network of researchers, centers of excellence, and technology platforms,

(ii) Facilitating collaborations among this network, including across institutions, geographies, and disciplines,

(iii) Leveraging each Party's technical capabilities and enabling access to tools and platforms to accelerate discovery through translation,

(iv) Openly sharing Data and Materials related to a Party's Project on the terms of these Principles, and

(v) Together, pursuing new hypotheses, unlocking intractable problems, and finding new solutions for global health challenges, pursuant to each Party's Grant Agreements (collectively, the "**Purpose**").

(c) The Collaboratory is not a separate legal entity, but is an agreement among the Parties to facilitate collaboration among the Parties and their respective Projects in order to create a collaborative network leveraging each Party's particular expertise and access to specialist resources for purposes of furthering the Global Access Objectives.

(d) Each Party (a) desires to collaborate, is currently collaborating, or is in consideration to collaborate with one or more Parties for the purpose of carrying out a Project, and

(b) desires to be funded, is currently funded, or is in consideration for funding by the Foundation to support a Project. When described as taking any action related to a Project (including, without limitation, receiving notices or providing permissions), each Party will take such action through such Party's principal investigator. To help organize the Collaboratory network, three categories of Parties are considered in these Principles, all of which are subject to the same terms:

(i) "**Platform Partner**" means a Party that has agreed to participate in the Collaboratory and provide a service, scientific expertise, or access to a research platform in support of the Platform Projects. Platform Partners are listed at the following page of the Collaboratory Portal: https://ghdiscoverycollaboratory.org/platforms.

(ii) "**Collaborator**" means any Party that is not a Platform Partner. Collaborators can include Hubs. Collaborators are listed at the following page of the Collaboratory Portal: https://ghdiscoverycollaboratory.org/about/collaborating-institutions.

(iii) "**Discovery Hub**" or "**Hub**" means a specific type of Collaborator that has agreed to participate in the Collaboratory and share their technical expertise and capabilities with other Parties. Hubs have received long-term funding by the Foundation to sustain their core capabilities, develop new technologies, and apply these across a continually replenishing portfolio of global health programs, including Collaboratory Programs. Hubs are designated at the Foundation's discretion and are listed at the following page of the Collaboratory Portal: https://ghdiscoverycollaboratory.org/about/hubs.

2. **Defined Terms**. For the purposes of these Principles, the following terms shall have their respective meanings as set forth in this Section 2, and grammatical variations have corresponding meanings. All capitalized terms used but not defined in this Section 2 have the respective meanings set forth in these Principles.

"**Affiliate**" means any business entity controlled by, controlling or under common control of a Party. 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.

"**Background Technology**" means, with respect to a Party, any and all products, services, processes, technologies, materials, software, data, other innovations and intellectual property created by such Party or a third party prior to or outside of such Party's Project used as part of a Project, or that otherwise does not constitute a Funded Development.

"**Collaboratory Portal**" means a web interface and associated functionality and storage provided at https://ghdiscoverycollaboratory.org (a) that will list all Parties to the Collaboratory, (b) through which Parties will (i) request access to the platforms and related services and expertise provided by the Platform Partners, and (ii) be provided access to stored documents established by Platform Partners, and (c) that will store (i) the Project SOWs, and (ii) any related research agreement or material transfer agreement. Platform Partners may also keep separately the Project SOWs, Project Cost Estimate and any related research agreement or material transfer agreement.

"**Confidential Information**" means (a) 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 Party, and (b) 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.

"**Data**" means recorded information generated in the performance of a Project, including Data related to gene sequences.

"**Funded Development**" means any products, services, processes, technologies, materials, software, data, other innovations, and intellectual property resulting from a Project (including modifications, improvements, and further developments to Background Technology).

"**Global Access Objectives**" means (a) the prompt and broad dissemination of knowledge and information (including Data) gained from a Project within the scientific community, and (b) facilitating the availability and accessibility of Funded Developments at an affordable price to people most in need within developing countries. More information about the Global Access Policy can be found at the following link: http://globalaccess.gatesfoundation.org/.

"**Manuscript**" means, with respect to a proposed Publication, the latest draft of the proposed Publication, together with all supporting data and information reasonably necessary to support the results or conclusions of such proposed Publication.

"**Materials**" will have the meaning set forth in each of the research agreement or material transfer agreement that is the legal instrument used by Collaborators to transfer Materials to a Platform Partner or other Collaborators in the conduct of a Platform Project or Collaboratory Program (as applicable).

"**Project**" is defined above in 1(a). The Collaboratory supports Projects in two general categories:

(i) "**Platform Project**" means any Project for which (a) a Project SOW exists, (b) a Platform Partner provides the Foundation and Parties access to best-in-class research services, and (c) the relevant Platform Partner, Collaborator(s) and the Foundation have agreed to. Each Platform Project will be recorded in the Collaboratory Portal.

(ii) "**Collaboratory Program**" means any Project that is not a Platform Project, and for which (a) a Project SOW exists, and (b) the relevant Parties and the Foundation have agreed to. Collaboratory Programs often involve one or more of the following elements (x) multiple Parties working together to address specific, unsolved problems in global health, (y) developing innovative technologies with application to global health, and/or (z) deploying tools for data access and integration across indications, disciplines, and/or geographies. Each Collaboratory Program will be recorded in the Collaboratory Portal.

"**Project Cost Estimate**" means the estimated costs for all activities represented in a Project SOW that is generated by the Parties (or, if applicable, the Platform Partner(s)). The Foundation will review and approve all Project Cost Estimates before the Parties implement a Project Cost Estimate to a Project SOW. Unless otherwise agreed by the Platform Partners

concerned, the Project Cost Estimate of a Platform Project is not shared with the Collaborators to the Platform Project.

"**Project Statement of Work**" or "**Project SOW**" is the technical description of a Project (including a description of how data sharing principles for the Project will be met, and, as applicable, the Project goals, Project-specific activities, Materials, experimental design, deliverables, Project Cost Estimate, and timelines) to be undertaken between Parties and agreed to by the Foundation and each Party, to the extent not addressed in the applicable Grant Agreement. An agreed-to Project SOW will be stored in the Collaboratory Portal.

"**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**").

3. **List of Collaboratory Parties**. The Foundation will continuously publish a list of the Parties on the Collaboratory Portal and may modify that list from time to time. The Foundation will notify all Parties of any such modifications.

4. **Collaborative Activities**.

(a) Each Party will perform its Project and otherwise act in a manner consistent with the Purpose and the terms of these Principles, the associated Grant Agreement, and the associated Project SOW. To the extent the Purpose, these Principles or the Project SOW conflict with a Grant Agreement, the Grant Agreement shall prevail.

(b) The Parties agree to discuss in good faith potential collaborations with each other consistent with the Purpose. Such collaborations may include, for example, arranging for a Party's principal investigator or other scientists to conduct research or perform a Party's Project and use another Party's campus.

(c) Each Party may engage (sub)contractors, (sub)grantees or other third parties ("**Subcontractors**") in its discretion to assist with such Party's Project, provided that (i) such Subcontractors' rights are subject to the terms of these Principles and (ii) such Party will cause any such Subcontractor to enter into a valid, written agreement with terms and conditions consistent with the applicable terms and conditions of these Principles. Each Party will be responsible for all acts or omissions of its Subcontractors.

5. **Sharing of Data and Material**.

(a) Each Party acknowledges that they are required to share Data with other Parties and with the Foundation in accordance with the terms of these Principles, including the confidentiality terms set forth in Section 6.

(b) No Party may assert patent rights, database rights, copyrights, or other rights in Data to interfere with another Party or the Foundation in implementing a Project, to the extent such Party is engaged in activities reasonably within the scope of such Project.

(c) Data must be collected, maintained and used in accordance with the necessary informed consent and regulatory approval (if applicable) in support of these Principles.

(d) The Parties will work with the Foundation to determine the process by which Materials and/or Data will be physically or electronically transferred among the Parties and the Foundation, in accordance with the following principles:

(i) Costs associated with Material and/or Data sharing activities, including costs to ensure that the Data is in a form compliant with applicable laws (e.g., anonymized) will be incorporated into the budget and the associated Grant Agreement.

(ii) The Parties to a Project will enter into one or more research agreements or material transfer agreements to enable such transfers of Materials or Data between the Parties to the Project. Unless otherwise agreed by the relevant Parties, with respect to each Project, the Parties to such Project will use a material transfer agreement substantially similar to the Uniform Biological Material Transfer Agreement, a copy of which is attached as Annex A, which may be modified by such Parties as necessary to address issues specific to the Materials transfer subject to the agreement, including the transfer of human tissue. The Foundation reserves the right to review all such agreements to ensure there are no impediments to the Global Access Objectives. For a given Platform Project, the Platform Partners will determine which research agreement or material transfer agreement should be provided to a Collaborator participating in the Platform Project. The Parties agree that any inconsistency between these Principles and a research or material transfer agreement as used in a Project will be resolved in favor of these Principles.

(iii) The Parties will be obliged to share Data generated by any such Party under a Project with the other Parties and the Foundation following a reasonable period of time as detailed in the associated Project SOW and not to exceed the first or second periods as follows:

(1) First Period of Delay of Data Sharing: not to exceed six (6) months following receipt of the Data by a Party or Parties or until the day a Manuscript generated from the Data is Published, whichever comes first (the "**First Period of Delay**"); and

(2) An Extended Period of Delay of Data Sharing: in the event that the Data is specific sequence information (including protein, nucleic acid, antibody or T cell receptor sequence) to be used in a formulation or a specific formulation itself and the Party concerned intends to make use of the Data when seeking patent protection, the period of delay may be extended (the "**Extended Period of Delay**") and 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 of Delay, but in any case not to exceed a cumulative total of eighteen (18) months following receipt of the Data by the Party. Notwithstanding the foregoing, a Party taking advantage of the Extended Period of Delay shall submit Blinded Data for sharing with the other Parties. "**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.

(iv) For Data where standardized data formats, metadata standards and repositories exist, such as for certain genomic and transcriptomic data, the Party will provide the Foundation and other Parties an appropriate link and identifier (e.g., accession number) to the data.

Publicly available repositories are listed at the following page of the Collaboratory Portal: https://ghdiscoverycollaboratory.org/data-access-and-integration/repositories. Parties that wish to submit Data to repositories that aren't listed in this link should provide the Foundation with links and information regarding the unlisted repository. The Foundation will discuss with the Party's principal investigator as to whether the unlisted repository meets the Data access requirements of these Principles and, if so, it will be circulated to the Parties and, if there are no objections within ninety (90) days, it will be added to the Collaboratory Portal link provided in this Section 5(d)(iv). A Project SOW will list which repository (or repositories) will be used for the corresponding Project.

(v) For Data where standardized data formats, metadata standards and repositories do not presently exist, the Foundation will work with the relevant Party to establish necessary and appropriate formats, standards, and identify or establish a repository by which the Data will be shared.

(vi) When Data is Published or otherwise publicly disseminated by a Party, any entity which Published or otherwise publicly disseminated the Data is required to acknowledge the Party that generated the Data and the Party that requested the services that led to the generation of the Data.

(vii) Prior to Publishing on Data generated under a Project, the Party that is the author of the Publication must provide a copy of the Manuscript to the Party that generated or requested the Data at least thirty (30) days prior to submission for Publication and shall reasonably consider any comments provided.

(viii) Authorship guidelines will be in accordance with those of the International Committee of Medical Journal Editors, or other generally recognized standards.

(ix) All Publications on Data generated under a Project shall conform with the Global Access Objectives and 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 Party.

6. **Confidentiality**.

(a) The exchange of Confidential Information of the Parties will be governed by this Section 6. The Parties are interested in examining and evaluating the other Parties' Confidential Information for the purpose of carrying out their own activities within the corresponding Project(s) (the "**Limited Purpose**"). In the event that there are any conflicts between the provisions set forth below and those set forth in the rest of these Principles, the provisions of the rest of these Principles shall control except as otherwise expressly stated in this Section 6.

(b) Each Party (the "**Disclosing Party**") may, at its own discretion, disclose certain Confidential Information owned or rightfully possessed by it to any other Party (the "**Receiving Party**").

(c) Each Receiving Party agrees that it will:

(i) use the Confidential Information received from a Disclosing Party solely for the Limited Purpose;

(ii) 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

(iii) 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 Limited Purpose as well as for any unauthorized disclosure directly resulting from their failure to exercise such reasonable care.

(d) Notwithstanding anything to the contrary in this Section 6, the Receiving Party shall have no obligation with respect to the Confidential Information received from a Disclosing Party to the extent such information is:

(i) already known by the Receiving Party at the time of disclosure as can be demonstrated by competent proof;

(ii) publicly known, or subsequently becomes publicly known, without the wrongful act or breach of this Section 6 by the Receiving Party;

(iii) 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;

(iv) approved for release or disclosure by written authorization of the Disclosing Party; or

(v) 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.

(e) In the event that the Receiving Party, or anyone to whom the Receiving Party transmits the Confidential Information pursuant to these Principles, becomes required to disclose any such Confidential Information pursuant to any competent judicial or government request, requirement or order, the Receiving Party will, to the extent permitted by applicable law, take 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 will take reasonable steps to ensure 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 Section 6.

(f) 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 Limited Purpose and/or to make decisions or render advice in connection with the Limited Purpose and who shall be informed of the existence of this Section 6 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 Section 6.

(g) Subject to exemptions and limitations elsewhere in this Section 6, the obligations of Section 6(c) herein shall remain in effect for each subject disclosure of Confidential Information for a period of three (3) years from date of the termination of the appertaining Projects for which Confidential Information has been transferred.

(h) Unless otherwise expressly agreed upon by the Disclosing Party and the Receiving Party, (i) no rights additional to those enumerated in Section 6(c) in the Confidential Information are provided to any Party 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.

(i) Except as allowed under Section 6(d), above, no Party shall be entitled to use the Confidential Information provided by the Disclosing Party for commercial purposes without a separate written agreement to that effect between the Disclosing Party, the Receiving Party and the Foundation.

(j) 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 Section 6 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.

(k) 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.

7. **Withdrawal**.

(a) These Principles will continue in full force and effect with respect to each Party unless and until (i) such Party withdraws from the Collaboratory pursuant to Section 7(b) below, (ii) such Party's Grant Agreement expires or is terminated, or (iii) such Party breaches any of the conditions of these Principles.

(b) A Party may withdraw its participation in the Collaboratory upon sixty (60) days' prior written notice to the Foundation.

(c) Termination, whether in whole or with respect to a Party's participation in this Collaboratory, does not affect any rights or obligations established prior to such termination or the participation of any other Party. Without limiting the generality of the foregoing, Sections 5, 6, 7, 8, 9, 10, 12, 13, 14, 15, 16, 17, 18 and 19 of these Principles survive any termination of these Principles (whether in whole or with respect to a particular Party's participation in this Collaboratory).

8. **Compliance with Laws**. In conducting its activities under these Principles, each Party agrees to comply with all applicable laws and regulations, including but not limited to the antitrust and/or competition laws of governing jurisdictions.

9. **No Conflict**. To the best of each Party's knowledge and as of the effective date of these Principles, each Party represents, warrants and covenants that agreements entered into or obligations assumed by the Party prior to entering into these Principles (or that will be entered into or assumed thereafter) do not and will not prohibit or prevent the Party from performing its obligations under these Principles.

10. **Third-Party Beneficiary**. The Parties acknowledge and agree that the Foundation is an intended third-party beneficiary of these Principles.

11. **Publicity**. Any Party may publicize the fact of the existence of the Collaboratory, their membership and descriptions of the Collaboratory in a manner consistent with these Principles; provided, however, that any press release related to the Collaboratory must be pre-approved in writing by the Foundation.

12. **Party Responsibilities**. No Party makes any warranties, express or implied as to any matter whatsoever, including without limitation, the Collaboratory results, its Materials, or any Funded Development, process or product, whether tangible or intangible, conceived, discovered, or developed under a Project or in connection with the Collaboratory; or the ownership, merchantability or fitness for a particular purpose of any Funded Development or product made under a Project or that the use of any materials, works or information provided in connection with the Collaboratory, will not constitute or result in infringement of third-party rights. Each Party is responsible and liable to the other Parties only for its own acts and omissions, and the acts and omissions of its trustees, directors, officers, employees, students, and agents, relating to a Project or the use or Publication of any Funded Development. These Principles make no assurance of indemnification.

13. **Non-Debarment Certification**. Each Party represents and warrants that neither it nor or any of its Subcontractors, employees or principals performing any acts in connection with these Principles is debarred, suspended, or proposed for debarment by the U.S. Food and Drug Administration ("**FDA**") or any agency of the U.S. Federal Government or any foreign and applicable equivalent of the FDA ("**Applicable Governmental Authority**"). Further, each Party will provide prompt written notice to the Foundation if any such Subcontractor, employee or principal is or becomes debarred, suspended, or proposed for debarment by the FDA or an Applicable Governmental Authority.

14. **Transition to the Collaboratory**.

(a) The Parties acknowledge that the Collaboratory is a continuation of the GH-VAP, and the Parties further acknowledge that the Foundation expects each Party to execute these Principles to enable a smooth transition to the Collaboratory and Collaboratory Portal. The Collaboratory Portal will go live on November 30, 2021. The Parties acknowledge that any data and information that may be stored on the GH-VAP portal ("**GH-VAP Portal**") will migrate to the Collaboratory Portal as of such date. The GH-VAP Portal will no longer be active as of November 30, 2021.

(b) Following a Party's execution of these Principles, these Principles will govern such Party's activities, rights and obligations with respect to all future Projects and any active projects entered into under the previous GH-VAP DSPA (such active projects, an "**Active GH-VAP Project**"). Without limiting the foregoing, solely with respect to the parties to any Active GH-VAP Project who have not executed these Principles, the GH-VAP DSPA will continue to govern such Active GH-VAP Projects and such parties will have access to the Collaboratory Portal for the duration of such Active GH-VAP Project, so long as a statement of work has been approved on or before December 17, 2021 (an "**Active GH-VAP Project SOW**"). Despite the previous sentence, each party to the GH-VAP DSPA is strongly encouraged to promptly execute these Principles, and no new Project SOW nor any amendment to an Active GH-VAP Project SOW will be approved after December 17, 2021, unless and until all parties to such statements of work have executed these Principles.

(c) If, as of July 1, 2022, any party to the GH-VAP DSPA or any Active GH-VAP Project SOW is still working on an Active GH-VAP Project but has not executed these Principles, such party's access to the Collaboratory Portal will be suspended unless such party and the Foundation can agree to an alternative solution in good faith.

15. **Severability**. If any provision of these Principles 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. **Wavier**. No waiver of any term, provision or condition of these Principles, 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 these Principles.

17. **Force Majeure.** No Party shall be liable for any failure to perform as required by these Principles 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.

18. **Notice**. Any notice or communication required or permitted to be given hereunder must be in writing signed or authorized by the Party giving notice, and may be delivered by hand, deposited with an overnight courier, sent by confirmed email, or mailed by registered or certified mail, return receipt requested, postage prepaid, in each case to the address of the receiving Party

as identified herein or at such other address as may hereafter be furnished in writing by such Party to the other Parties. Such notice will be deemed to have been given as of the date it is delivered.

19. **Non-Assignment**. No Party may assign these Principles or the rights or obligations hereunder, in whole or in part, whether voluntarily, by operation of law or otherwise, without the prior written consent of the Foundation, and any purported assignment in violation of the foregoing will be void.

Version	**Updates**
November 30, 2021	Original
December 7, 2021	Added active web links to https://ghdiscoverycollaboratory.org

[Signature Page Follows.]

SIGNATORY

to the

Global Health Discovery Collaboratory
Guiding Principles

IN WITNESS WHEREOF, the undersigned Party hereby executes these Principles and has caused these Principles to be executed by its duly-authorized representative.

_____

Signed on Behalf of (Identify Organization):

_____

By:_____

Name:_____

Title:_____

Address: _____

_____

_____

Date Signed:_____

IN WITNESS WHEREOF, the undersigned acknowledges that it has read and understood the terms and conditions set forth in Section 6 and agrees to comply therewith.

Read and Understood By (Principal Investigator):

_____

Name:_____

Title: _____

Date Signed:_____

[***Separate signature page to be completed by each Party***.]

ANNEX A

Form of the Uniform Biological Material Transfer Agreement

1. Definitions:

1.1 PROVIDER: Organization providing the ORIGINAL MATERIAL. The name and address of this party will be specified in an implementing letter.

1.2 PROVIDER SCIENTIST: The name and address of this party will be specified in an implementing letter.

1.3 RECIPIENT: Organization receiving the ORIGINAL MATERIAL. The name and address of this party will be specified in an implementing letter.

1.4 RECIPIENT SCIENTIST: The name and address of this party will be specified in an implementing letter.

1.5 ORIGINAL MATERIAL: The description of the material being transferred will be specified in an implementing letter.

1.6 MATERIAL: ORIGINAL MATERIAL, PROGENY, and UNMODIFIED DERIVATIVES. The MATERIAL shall not include:

(a) MODIFICATIONS, or

(b) other substances created by the RECIPIENT through the use of the MATERIAL which are not MODIFICATIONS, PROGENY, or UNMODIFIED DERIVATIVES.

1.7 PROGENY: Unmodified descendant from the MATERIAL, such as virus from virus, cell from cell, or organism from organism.

1.8 UNMODIFIED DERIVATIVES: Substances created by the RECIPIENT which constitute an unmodified functional subunit or product expressed by the ORIGINAL MATERIAL. Some examples include: subclones of unmodified cell lines, purified or fractionated subsets of the ORIGINAL MATERIAL, proteins expressed by DNA/RNA supplied by the PROVIDER, or monoclonal antibodies secreted by a hybridoma cell line.

1.9 MODIFICATIONS: Substances created by the RECIPIENT which contain/incorporate the MATERIAL.

1.10 COMMERCIAL PURPOSES: The sale, lease, license, or other transfer of the MATERIAL or MODIFICATIONS to a for-profit organization. COMMERCIAL PURPOSES shall also include uses of the MATERIAL or MODIFICATIONS by any organization, including RECIPIENT, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the MATERIAL or MODIFICATIONS to a for-profit organization.

However, industrially sponsored academic research shall not be considered a use of the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES per se, unless any of the above conditions of this definition are met.

1.11 NONPROFIT ORGANIZATION(S): A university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute. As used herein, the term also includes government agencies.

2. Terms and Conditions of this Agreement:

2.1 The PROVIDER retains ownership of the MATERIAL, including any MATERIAL contained or incorporated in MODIFICATIONS.

2.2 The RECIPIENT retains ownership of:

(a) MODIFICATIONS (except that, the PROVIDER retains ownership rights to the MATERIAL included therein), and

(b) those substances created through the use of the MATERIAL or MODIFICATIONS, but which are not PROGENY, UNMODIFIED DERIVATIVES or MODIFICATIONS (i.e., do not contain the ORIGINAL MATERIAL, PROGENY, UNMODIFIED DERIVATIVES). If either 2 (a) or 2 (b) results from the collaborative efforts of the PROVIDER and the RECIPIENT, joint ownership may be negotiated.

2.3 The RECIPIENT and the RECIPIENT SCIENTIST agree that the MATERIAL:

(a) is to be used solely for teaching and academic research purposes;

(b) will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of the PROVIDER;

(c) is to be used only at the RECIPIENT organization and only in the RECIPIENT SCIENTIST's laboratory under the direction of the RECIPIENT SCIENTIST or others working under his/her direct supervision; and

(d) will not be transferred to anyone else within the RECIPIENT organization without the prior written consent of the PROVIDER.

2.4 The RECIPIENT and the RECIPIENT SCIENTIST agree to refer to the PROVIDER any request for the MATERIAL from anyone other than those persons working under the RECIPIENT SCIENTIST's direct supervision. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agrees to make the MATERIAL available, under a separate implementing letter to this Agreement or other agreement having terms consistent with the terms of this Agreement, to other scientists (at least those at NONPROFIT ORGANIZATION(S)) who wish to replicate the RECIPIENT SCIENTIST's research; provided

that such other scientists reimburse the PROVIDER for any costs relating to the preparation and distribution of the MATERIAL.

(a) The RECIPIENT and/or the RECIPIENT SCIENTIST shall have the right, without restriction, to distribute substances created by the RECIPIENT through the use of the ORIGINAL MATERIAL only if those substances are not PROGENY, UNMODIFIED DERIVATIVES, or MODIFICATIONS.

(b) Under a separate implementing letter to this Agreement (or an agreement at least as protective of the PROVIDER's rights), the RECIPIENT may distribute MODIFICATIONS to NONPROFIT ORGANIZATION(S) for research and teaching purposes only.

(c) Without written consent from the PROVIDER, the RECIPIENT and/or the RECIPIENT SCIENTIST may NOT provide MODIFICATIONS for COMMERCIAL PURPOSES. It is recognized by the RECIPIENT that such COMMERCIAL PURPOSES may require a commercial license from the PROVIDER and the PROVIDER has no obligation to grant a commercial license to its ownership interest in the MATERIAL incorporated in the MODIFICATIONS. Nothing in this paragraph, however, shall prevent the RECIPIENT from granting commercial licenses under the RECIPIENT's intellectual property rights claiming such MODIFICATIONS, or methods of their manufacture or their use.

2.5 The RECIPIENT acknowledges that the MATERIAL is or may be the subject of a patent application. Except as provided in this Agreement, no express or implied licenses or other rights are provided to the RECIPIENT under any patents, patent applications, trade secrets or other proprietary rights of the PROVIDER, including any altered forms of the MATERIAL made by the PROVIDER. In particular, no express or implied licenses or other rights are provided to use the MATERIAL, MODIFICATIONS, or any related patents of the PROVIDER for COMMERCIAL PURPOSES.

2.6 If the RECIPIENT desires to use or license the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES, the RECIPIENT agrees, in advance of such use, to negotiate in good faith with the PROVIDER to establish the terms of a commercial license. It is understood by the RECIPIENT that the PROVIDER shall have no obligation to grant such a license to the RECIPIENT, and may grant exclusive or non-exclusive commercial licenses to others, or sell or assign all or part of the rights in the MATERIAL to any third party(ies), subject to any pre-existing rights held by others and obligations to the Federal Government.

2.7 The RECIPIENT is free to file patent application(s) claiming inventions made by the RECIPIENT through the use of the MATERIAL but agrees to notify the PROVIDER upon filing a patent application claiming MODIFICATIONS or method(s) of manufacture or use(s) of the MATERIAL.

2.8 Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. The PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO 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 MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

2.9 Except to the extent prohibited by law, the RECIPIENT assumes all liability for damages which may arise from its use, storage or disposal of the MATERIAL. 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 of the MATERIAL by the RECIPIENT, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the PROVIDER.

2.10 This agreement shall not be interpreted to prevent or delay publication of research findings resulting from the use of the MATERIAL or the MODIFICATIONS. The RECIPIENT SCIENTIST agrees to provide appropriate acknowledgement of the source of the MATERIAL in all publications.

2.11 The RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations, including Public Health Service and National Institutes of Health regulations and guidelines such as, for example, those relating to research involving the use of animals or recombinant DNA.

2.12 This Agreement will terminate on the earliest of the following dates:

(a) when the MATERIAL becomes generally available from third parties, for example, though reagent catalogs or public depositories or

(b) on completion of the RECIPIENT's current research with the MATERIAL, or

(c) on thirty (30) days written notice by either party to the other, or

(d) on the date specified in an implementing letter, provided that:

i. if termination should occur under 13(a), the RECIPIENT shall be bound to the PROVIDER by the least restrictive terms applicable to the MATERIAL obtained from the then-available resources;

ii. if termination should occur under 13(b) or (d) above, the RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the PROVIDER, return or destroy any remaining MATERIAL. The RECIPIENT, at its discretion, will also either destroy the MODIFICATIONS or remain bound by the terms of this agreement as they apply to MODIFICATIONS; and

iii. in the event the PROVIDER terminates this Agreement under 13(c) other than for breach of this Agreement or for cause such as an imminent health risk or patent infringement, the PROVIDER will defer the effective date of termination for a period of

up to one year, upon request from the RECIPIENT, to permit completion of research in progress. Upon the effective date of termination, or if requested, the deferred effective date of termination, RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the PROVIDER, return or destroy any remaining MATERIAL. The RECIPIENT, at its discretion, will also either destroy the MODIFICATIONS or remain bound by the terms of this agreement as they apply to MODIFICATIONS.

2.13 Paragraphs 2.5, 2.8, and 2.9 shall survive termination.

2.14 The MATERIAL is provided at no cost, or with an optional transmittal fee solely to reimburse the PROVIDER for its preparation and distribution costs. If a fee is requested by the PROVIDER, the amount will be indicated in an implementing letter.

Each party is signing this agreement on the date stated under that party's signature.

[*Enter Provider's Full Name*]

By:_____

Name:_____

Title:_____

Address: _____

_____

_____

Date Signed:_____

[*Enter Recipient's Full Name*]

By:_____

Name:_____

Title:_____

Address: _____

_____

_____

Date Signed:_____

Scientist:

_____

Name:_____

Title: _____

Date Signed:_____