

This Material Transfer Agreement ("MTA") is between the RECIPIENT and the American Type Culture Collection ("ATCC®"), a not-for-profit organization having its offices at 10801 University Blvd. Manassas, Virginia 20110 which is acting in the capacity of a contractor to the National Institute of Allergy and Infectious Disease ("NIAID"), an Institute of the National Institutes of Health ("NIH"), an agency of the U.S. Department of Health and Human Services ("HHS"). The U.S. Government-funded programs are separate and distinct from other collections at the ATCC.

TERMS AND CONDITIONS

DEFINITIONS

COLLABORATOR: Any third party, other than a CONTRIBUTOR, collaborating with RECIPIENT on a project funded by the same U.S. Government grant, cooperative agreement or contract as RECIPIENT, for the purpose(s) and during the term of that funding agreement, provided that party is also registered with ATCC for access to the PROGRAM and has executed an MTA and INTER- REGISTRANT TRANSFER AGREEMENT for that MATERIAL.

COMMERCIAL PURPOSES: For purposes of this Agreement:

- (1) The term COMMERCIAL PURPOSES means the sale, license, lease, export, transfer or other distribution of MATERIAL or MODIFICATIONS to a third party for financial gain or other commercial purposes and/or the use of MATERIAL: (a) to provide a service to a third party for financial gain; (b) to produce or manufacture products for general sale or products for use in the manufacture of products ultimately intended for general sale; (c) in connection with ADME (Absorption, Distribution, Metabolism and Excretion) testing; (d) in connection with drug potency or toxicity testing which does not include either screening multiple cell lines for potential inclusion in a screening assay system or screening multiple compounds in a system for internal research purposes only; (e) in connection with proficiency testing service(s), including but not limited to, providing the service of determining laboratory performance by means of comparing and evaluating calibrations or tests on the same or similar items or materials in accordance with predetermined conditions; or (f) for research conducted under an agreement wherein a for-profit entity receives a right whether actual or contingent to the results of the research.
- (2) The term COMMERCIAL PURPOSES does NOT include the use of MATERIAL or MODIFICATIONS for Industry Sponsored Academic Research or by any organization for a project funded by the U.S. Government through a grant, cooperative agreement or contract, and only for the purpose(s) of and during the term of that funding agreement. In any event, commercial sale of any product or service based on MATERIAL will require a commercial license from the CONTRIBUTOR if required by the CONTRIBUTOR at the time of deposit.

CONTRIBUTOR: Organization and/or individual providing ORIGINAL MATERIAL to ATCC for deposit into the PROGRAM. CONTRIBUTOR retains ownership rights to MATERIAL where applicable as defined on the PROGRAM'S Deposit form.

CONTRIBUTOR LICENSE: Separate agreement between CONTRIBUTOR and RECIPIENT stating terms and conditions for use of MATERIAL and/or MODIFICATIONS, as appropriate, for COMMERCIAL PURPOSES.

DULY AUTHORIZED SIGNATORY: An individual who is authorized to execute a binding document on behalf of the RECIPIENT institution.

INTER-REGISTRANT TRANSFER AGREEMENT: An agreement used by sending and receiving institutions to execute preauthorized 3rd party transfers of the PROGRAM's materials and modifications. U.S. Government grant, cooperative agreement or contract number under which MATERIAL is to be used, if any, and an updated abstract of proposed use, are to be submitted to the PROGRAM in connection with submitting the INTER-REGISTRANT TRANSFER AGREEMENT. Note: By providing ATCC with current or updated government grant or contract information you significantly facilitate requests for materials, especially when your research requirements exceed preauthorized quantities of materials.

LETTER OF TRANSFER: An acknowledgement of the MTA, as a check box on the website, checked by the RECIPIENT for each requested MATERIAL.



INDIVIDUAL MATERIAL TRANSFER AGREEMENT

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

MODIFICATIONS: Substances created by RECIPIENT which contain/incorporate a significant or substantial portion of MATERIAL.

ORIGINAL MATERIAL: The MATERIAL provided by CONTRIBUTOR to ATCC for deposit into the PROGRAM.

PROGENY: Unmodified descendant from MATERIAL, such as by way of non-limiting example: virus from virus, cell from cell, or microorganism from microorganism.

PROGRAM: NIAID funded government programs managed by ATCC.

RECIPIENT: Organization receiving ORIGINAL MATERIAL from the program through ATCC.

REGISTRANT: RECIPIENT's representative receiving and using MATERIAL.

SELECT AGENT: Specifically regulated pathogens and toxins as defined in 42 C.F.R. Part 73, 9 C.F.R. 331 and 9 CFR 121, including pathogens and toxins regulated by both HHS and USDA as announced in the Federal Register, and listed on the HHS Centers for Disease Control and Prevention website www.cdc.gov/.

UNMODIFIED DERIVATIVE: Substance created by RECIPIENT that constitutes an unmodified functional subunit or product not changed in form or character and expressed by ORIGINAL MATERIAL. Such non-limiting examples include: subclones of unmodified cell lines, purified or fractionated subsets of ORIGINAL MATERIAL, proteins expressed by DNA/RNA supplied by CONTRIBUTOR, or monoclonal antibodies secreted by a hybridoma cell line.

RECEIPT: SCOPE OF USE AND TRANSFER

Receipt. For each requested MATERIAL, RECIPIENT must agree to the LETTER OF TRANSFER, thereby acknowledging this agreed upon MTA, during the ordering process. The receiving REGISTRANT is also required to provide an updated abstract describing the proposed use of MATERIAL if the scope of use on file has changed. If MATERIAL will be used under a U.S. Government grant, cooperative agreement or contract, the REGISTRANT must identify to ATCC the number and title of the funding agreement in connection with submitting the request for MATERIAL.

Select Agents. To receive SELECT AGENTS, RECIPIENT must obtain necessary permits and written proof of approval from HHS (42 C.F.R. 71, 72, 73) or USDA (7 C.F.R. 331, 9 C.F.R. 121 and 122) to possess SELECT AGENTS, copies of which must be received by ATCC before MATERIAL will be shipped. RECIPIENT acknowledges that failure to comply with any laws, regulations or other requirements relating to SELECT AGENTS may result in civil and/or criminal penalties. RECIPIENT agrees to notify ATCC regarding all MODIFICATIONS of SELECT AGENTS that retain or can attain viability or bioactivity and agrees, upon request from ATCC, to deposit those MODIFICATIONS with the program through ATCC for purposes of reference. ATCC agrees that RECIPIENT may request distribution restrictions for these MODIFICATIONS.

Scope of Use. RECIPIENT may use MATERIAL and MODIFICATIONS for research purposes and in RECIPIENT's facility only and such use will occur only according to the contributor-assigned Release Category (as described in Commercial Purposes) for each MATERIAL. If RECIPIENT desires to use MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES and, if required to do so by CONTRIBUTOR for such COMMERCIAL PURPOSES, RECIPIENT agrees to negotiate in good faith with CONTRIBUTOR in advance of such use to establish the terms of an appropriate commercial CONTRIBUTOR LICENSE.

Inter-Registrant Transfer. An INTER-REGISTRANT TRANSFER AGREEMENT (IRTA) must be used to request approval for all 3rd party transfers of the program's material. 3rd party transfer requests of the program's material can only be made between current program REGISTRANTS. MATERIAL and MODIFICATIONS may be used or transferred to the facilities of COLLABORATOR subject to any restrictions in this Agreement and the applicable IRTA.

RECIPIENT AGREES THAT MATERIAL AND MODIFICATIONS WILL NOT BE USED IN HUMANS WITHOUT PRIOR WRITTEN PROOF TO ATCC OF REGULATORY APPROVAL FOR SUCH USE. Furthermore, if RECIPIENT has received such regulatory approval, RECIPIENT agrees to conduct the clinical research in accordance with applicable laws

and regulations or otherwise in accordance with U. S. Food and Drug Administration Good Clinical Practice (International Conference on Harmonisation E6: "Good Clinical Practice: Consolidated Guideline"; 62 CFR 25, 691 (1997)).

RECIPIENT ACKNOWLEDGES THAT MATERIALS DESIGNATED AS BIOSAFETY LEVEL 2 OR HIGHER CONSTITUTE KNOWN PATHOGENS OR TOXINS AND THEREFORE REQUIRE APPROPRIATE FACILITIES FOR THEIR USE. RECIPIENT ALSO ACKNOWLEDGES THAT OTHER MATERIALS NOT SO DESIGNATED AND MODIFICATIONS THEREOF MAY BE PATHOGENIC UNDER CERTAIN CONDITIONS.

OWNERSHIP OF MATERIAL AND INTELLECTUAL PROPERTY

Ownership of Material. Ownership of Material is defined by the CONTRIBUTOR through assignment of a Release Category for MATERIAL as described in Commercial Purposes. If so assigned, CONTRIBUTOR retains ownership rights to MATERIAL, including MATERIAL contained or incorporated in MODIFICATIONS. CONTRIBUTOR also retains rights to any intellectual property it owns in MATERIAL. RECIPIENT retains ownership of: (a) MODIFICATIONS (except that CONTRIBUTOR retains ownership rights to MATERIAL included therein) and (b) those substances created through the use of MATERIAL or MODIFICATIONS, but which do not contain MATERIAL. If (a) or (b) results from collaborative efforts of CONTRIBUTOR and RECIPIENT, joint ownership may be negotiated. RECIPIENT understands that the U.S. Government may request RECIPIENT to deposit any or all MODIFICATIONS into the program for reference purposes.

Inventions and Patents. RECIPIENT is free to file patent application(s) claiming inventions made by RECIPIENT through the use of MATERIAL or MODIFICATIONS. RECIPIENT will retain ownership of any inventions and patents or patent applications directed thereto that it makes using MATERIAL. RECIPIENT acknowledges that use of MATERIAL or MODIFICATIONS may be subject to the intellectual property rights of third parties other than CONTRIBUTOR, and ATCC MAKES NO REPRESENTATION OR WARRANTY THAT SUCH RIGHTS DO NOT EXIST. RECIPIENT shall have sole responsibility for obtaining any appropriate intellectual property license(s) required to use MATERIAL or MODIFICATIONS.

If RECIPIENT desires to use MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES and, if required to do so by CONTRIBUTOR for such COMMERCIAL PURPOSES, RECIPIENT agrees to negotiate in good faith with CONTRIBUTOR in advance of such use to establish the terms of an appropriate commercial CONTRIBUTOR LICENSE. RECIPIENT also agrees to provide written proof of license to ATCC in order to receive MATERIAL. RECIPIENT understands that CONTRIBUTOR shall have no obligation to grant such a CONTRIBUTOR LICENSE to RECIPIENT.

Commercial Purposes. Recipient agrees that before a reagent is used for COMMERCIAL PURPOSES, such use will occur only according to the contributor-assigned Release Category described below.

- A - Reagent may be used for Commercial Purposes without an agreement with the CONTRIBUTOR.
- B - Recipient agrees to negotiate in good faith to share with the CONTRIBUTOR's institution the income arising from commercializing the reagent.
- C - Recipient must sign an agreement with the CONTRIBUTOR's institution for Commercial Purposes prior to receiving the reagent.
- D - Recipient must select Release Category B or C prior to receiving the reagent.
- E - Recipient must not use or incorporate the reagent for Commercial Purposes. (Reagent cannot ever be distributed from our program to a commercial institution for ANY use. Reagent will be distributed for non-profit use ONLY).

Note: Reagent CONTRIBUTORS may change their Release Category assignment. Recipient is expected to abide by the reagent assignment that is in place at the time the reagent is received. If Recipient wishes to use the reagent under the terms of a revised release category assignment, then Recipient must submit a new reagent request.

Trademarks. Nothing in this Agreement shall be construed to affect ATCC's rights, title and interests in and to trademarks registered or owned by the ATCC or the U.S. Government and any and all ATCC catalog numbers or ATCC-specific designations of biological materials sold by the ATCC.

Dispute Resolution. Any disputes arising under this Agreement shall be tried exclusively in the United States District Court for the Eastern District of Virginia or if subject matter jurisdiction does not exist in that court, then in the state courts of Virginia for Prince William County, and RECIPIENT hereby expressly consents to, submits to and waives any objection



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to the jurisdiction of such courts; provided however, if RECIPIENT is a US Federal or State non-profit organization; then any disputes arising under this Agreement shall be tried exclusively in a court of competent jurisdiction.

CONFIDENTIALITY: PUBLICATIONS

RECIPIENT agrees to treat in confidence, for a period of three (3) years from the date of its disclosure, any of the programs' or CONTRIBUTOR's written information about MATERIAL that is stamped "CONFIDENTIAL" except for information that was previously known to RECIPIENT or that is or becomes publicly available or which is disclosed to RECIPIENT without a confidentiality obligation. Any oral disclosures from the PROGRAM or CONTRIBUTOR shall be identified as confidential by notice delivered to RECIPIENT within ten (10) days after the date of oral disclosure.

RECIPIENT may publish or otherwise publicly disclose the results of the work with MATERIAL, but if RECIPIENT received confidential information from the PROGRAM or CONTRIBUTOR, then only after the source of the confidential information has had thirty (30) days to review the proposed disclosure to determine whether it includes any CONFIDENTIAL information, except when a shortened time period under court order of the Freedom of Information Act, 5 U.S.C. § 552, pertains. RECIPIENT agrees to provide a copy of all publications relating to MATERIAL or MODIFICATIONS to ATCC for deposit into the PROGRAM.

In all publications and patent applications that reference MATERIAL or MODIFICATIONS, RECIPIENT agrees to acknowledge the PROGRAM and the PROGRAM'S catalog numbers if applicable, and any CONTRIBUTOR indicated through the PROGRAM as the source of ORIGINAL MATERIAL. RECIPIENT agrees that ATCC may inform CONTRIBUTOR of RECIPIENT'S identity if required to do so by law, by CONTRIBUTOR, or if MATERIAL is subject to an issued patent.

WARRANTY: WARRANTY DISCLAIMER

ATCC warrants that cells and microorganisms, excluding inactivated organisms, shall be viable upon shipment from ATCC for a period of thirty (30) days ("WARRANTY PERIOD"). ATCC warrants that MATERIAL shall meet the specifications on the certificate of analysis. The exclusive remedy for breach of this warranty is, at ATCC's option, replacement of MATERIAL. The exclusive remedy applies under the condition that RECIPIENT handles and stores MATERIAL as described in any accompanying documentation. To obtain the exclusive remedy, RECIPIENT must report the lack of viability to the PROGRAM'S Technical Service Department within the WARRANTY PERIOD. Any expiration date specified on shipment documentation for MATERIAL states the expected remaining useful life, but does not constitute a warranty or extend any applicable warranty period. **EXCEPT AS EXPRESSLY PROVIDED ABOVE, MATERIAL AND ANY TECHNICAL INFORMATION AND ASSISTANCE PROVIDED BY ATCC ARE PROVIDED "AS IS", WITHOUT WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TYPICALITY, SAFETY, ACCURACY AND NON-INFRINGEMENT.**

SAFETY: COMPLIANCE WITH LAWS

EXCEPT TO THE EXTENT PROHIBITED BY LAW, RECIPIENT ASSUMES ALL RISKS AND RESPONSIBILITY IN CONNECTION WITH RECIPIENT'S RECEIPT, HANDLING, STORAGE, DISPOSAL, INTERNAL TRANSFER AND USE OF MATERIAL AND MODIFICATIONS INCLUDING WITHOUT LIMITATION TAKING ALL APPROPRIATE SAFETY AND HANDLING PRECAUTIONS TO MINIMIZE HEALTH OR ENVIRONMENTAL RISK, AS WELL AS FOR ANY ADVERSE EVENTS RESULTING FROM RECIPIENT'S VIOLATION OF THE SECURITY REQUIREMENTS OR UNAUTHORIZED DISSEMINATION OF MATERIAL AND MODIFICATIONS. RECIPIENT IS SOLELY RESPONSIBLE FOR ITS COMPLIANCE WITH ALL APPLICABLE FEDERAL STATUTES, ORDINANCES, REGULATIONS AND GUIDELINES.

RECIPIENT hereby represents that RECIPIENT shall (1) ensure that only qualified personnel work with MATERIAL and MODIFICATIONS in proper facilities; (2) provide sufficient internal security to assure access to MATERIAL and MODIFICATIONS only by those individuals authorized to work with them; (3) not transfer, export, resell, or otherwise dispose of any MATERIAL or MODIFICATIONS to any third party under any circumstances without express written authorization from ATCC and the appropriate government agencies or as explicitly provided for within this Agreement; (4) not permit access to MATERIAL or MODIFICATIONS by foreign entities or individuals when to do so would be in violation



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of export control laws; (5) maintain adequate insurance coverage for liability to any party that might be injured by release of MATERIAL or MODIFICATIONS; (6) comply with all applicable federal, state, or local laws and regulations pertaining to MATERIAL or MODIFICATIONS or their handling, storage, use, transportation; and (7) unless requested otherwise by ATCC, destroy all MATERIAL according to accepted practices for destruction of biohazardous material upon completion of work or expiration or termination of this Agreement, whichever occurs first.

INDEMNIFICATION

RECIPIENT assumes all liability for damages that may arise from RECIPIENT's use, storage or disposal of MATERIAL and MODIFICATIONS. To the extent permitted under Federal or State law, RECIPIENT agrees that it will indemnify and hold harmless The U.S. Government, ATCC, their suppliers and CONTRIBUTORS from any claims, cost damages, or expenses.

LIMITATION OF LIABILITY

IN NO EVENT WILL ATCC, THE U.S. GOVERNMENT OR CONTRIBUTORS BE LIABLE FOR ANY SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND IN CONNECTION WITH OR ARISING OUT OF THIS MTA, MATERIAL, AND MODIFICATIONS (WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY, STATUTE OR OTHERWISE) EVEN IF ATCC HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. RECIPIENT AGREES THAT THE LIMITATIONS OF LIABILITY SET FORTH IN THIS AGREEMENT SHALL APPLY EVEN IF A LIMITED REMEDY PROVIDED HEREUNDER FAILS OF ITS ESSENTIAL PURPOSE.

SHIPPING

MATERIAL will be packaged and shipped in accordance with applicable laws and regulations. RECIPIENT is responsible for ensuring that all permits required for RECIPIENT to receive its order are obtained and that sufficient proof of such permits is provided to ATCC. ATCC will notify RECIPIENT when orders are submitted without the necessary permits, and RECIPIENT will have a two (2) month period after such notification to supply proof of the necessary permit(s) before an order will be cancelled. A processing fee will be charged if special processing or packaging is necessary. MATERIAL is shipped Free On Board (FOB) point of shipment, via carrier of ATCC's choice.

RECIPIENT agrees that REGISTRANT shall inform ATCC in writing of the date of receipt within five (5) working days of receiving MATERIAL undamaged or within twenty-four (24) hours of receipt or expected receipt if MATERIAL is damaged or lost. If MATERIAL is damaged or lost during shipment, ATCC will replace such MATERIAL, provided RECIPIENT has reported lost or damaged shipments to the applicable carrier and notified the PROGRAM'S Customer Service Department within twenty-four (24) hours.

TERMINATION

This MTA will be effective in perpetuity after the date of the last signature below unless and until terminated as provided hereunder. RECIPIENT may terminate this Agreement by written notice to ATCC at least thirty (30) days in advance of the desired date of termination. RECIPIENT understands that ATCC may terminate this Agreement at any time with written notice to RECIPIENT and REGISTRANT. On termination of this Agreement, RECIPIENT agrees that any remaining MATERIAL will be destroyed (unless requested by ATCC to return remaining MATERIAL) and to provide written proof thereof to ATCC and NIAID no later than thirty (30) days from the date of termination. Upon termination of this Agreement RECIPIENT agrees to discuss with ATCC and NIAID the disposition of MODIFICATIONS.

MISCELLANEOUS

RECIPIENT may not assign or otherwise transfer this Agreement or any rights or obligations under this Agreement, whether by operation of law or otherwise. Any attempted assignment or transfer will be void and of no force or effect. This MTA, all documents incorporated herein by reference, and INTER- REGISTRANT TRANSFER AGREEMENT required for subsequent transfer of MATERIAL constitute the entire agreement between ATCC and RECIPIENT with respect to MATERIAL and supersede all previous agreements or representations.



INDIVIDUAL MATERIAL TRANSFER AGREEMENT

RECIPIENT agrees to comply with any additional requirements of the CONTRIBUTOR as specified for a MATERIAL in the PROGRAM's catalog.

The above sections on OWNERSHIP OF MATERIAL AND INTELLECTUAL PROPERTY, CONFIDENTIALITY; PUBLICATIONS, WARRANTY; WARRANTY DISCLAIMER, INDEMNIFICATION, and LIMITATION OF LIABILITY shall survive expiration or earlier termination of this Agreement.

Signatures

READ AND UNDERSTOOD BY REGISTRANT

Registrant Printed Name _____ Phone Number _____

Position Description _____ Email _____

Institution _____

Address _____

Signature _____ Date _____

THE UNDERSIGNED SIGNATORY OF RECIPIENT REPRESENTS THAT HE OR SHE HAS THE AUTHORITY TO MAKE THE ABOVE REPRESENTATIONS ON BEHALF OF RECIPIENT AND FURTHER REPRESENTS THAT HE OR SHE IS LEGALLY AUTHORIZED TO ENTER INTO THIS BINDING AGREEMENT ON BEHALF OF RECIPIENT.

DULY AUTHORIZED SIGNATORY FOR RECIPIENT'S INSTITUTION

Signatory Printed Name _____ Phone Number _____

Position Description _____ Email _____

Institution _____

Address _____

Signature _____ Date _____

The completed and signed Material Transfer Agreement can be sent to ATCC by email, fax or postal mail:

Email: contact@HIVReagentProgram.org

Fax: (703) 365-2898

NIH HIV Reagent Program

American Type Culture Collection

10801 University Blvd.

Manassas, VA 20110-2209 USA

ATCC® is a registered trademark of the American Type Culture Collection.

FOR ATCC USE ONLY

Signature: _____ Printed Name: _____

Date: _____ Title: _____