NATIONAL INSTITUTES OF HEALTH

MATERIALS COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

This Materials Cooperative Research and Development Agreement ("M-CRADA") has been adopted for use by the Institutes and Centers ("ICs") of the National Institutes of Health ("NIH") for transfers of essential research material(s) from collaborators. This M-CRADA will be effective as of January 14, 2025 (the "Effective Date") and will be among NIH and the Centers for Disease Control and Prevention ("CDC"), on the one hand, and Gilead Sciences, Inc., hereinafter referred to as "Collaborator", on the other. "Party" means NIH, CDC, or Collaborator, "Parties" means NIH, CDC, and Collaborator, collectively. This M-CRADA consists of a copy of the NIH Model M-CRADA, as modified herein, a Signature Page, a Contacts Page, and a Summary Page. The master research plan ("Research Plan") is attached as Appendix A, which is incorporated herein by reference. The Research Plan contemplates additional CRADAs, clinical trial agreements, or incremental research plans (collectively, "Project Specific Agreements") which will set forth intended uses of the Collaborator Research Material and a more specific research plan or terms related to the research plan or clinical trial. Such Project Specific Agreements may be in the form of the appropriate model Public Health Services agreements existing as of the Effective Date, in each case to the extent that they do not conflict with this M-CRADA. Such model agreements will be subject to standard NIH and CDC policies and procedures related thereto, provided that such policies and procedures do not conflict with this M-CRADA. Collaborator will evaluate each incremental research plan in good faith but retains discretion on whether to participate in each such incremental research plan and provide the Collaborator Research Materials for the use contemplated therein. The Parties shall work cooperatively with respect to any such incremental research plan, which upon signature by the Parties, shall amend and supplement this M-CRADA. The Parties contemplate that any incremental research plan may include a request for Collaborator Research Materials from Collaborator. In the event of any conflict between the Research Plan and any Project-Specific Agreement, the terms of the Research Plan shall control. In the event of any conflict between any Project-Specific Agreement and the terms set forth in Articles 2, 3 or 4 of this M-CRADA, the terms set forth in Articles 2, 3 or 4 of this M-CRADA shall control. The Parties agree and acknowledge that this M-CRADA has been modified from the NIH IC-Collaborator M-CRADA model adopted 2009 and revised August 2012 (the "Form M-CRADA") and that all such changes are reflected herein. The following provisions from the Form M-CRADA will be addressed on an as-needed basis in the applicable Project Specific Agreement: Section 2 (Human origin Collaborator Research Materials; Human Subjects); Section 3 (Confidentiality; Publications); Section 4 (Control of Collaborator Research Material); and Section 5 (Warranty Disclaimer). This M-CRADA involves no exchange of personnel or of any resources other than as described in Appendix A. This M-CRADA is made under authority of the Federal Technology Transfer Act, 15 U.S.C. § 3710a, and is governed by its terms.

1. The Parties agree that the National Institute of Allergy and Infectious Diseases ("NIAID") will serve as the primary administrator of this M-CRADA, on behalf of NIH and CDC. NIH and CDC further agree to implement a Memorandum of Understanding or other appropriate agreement with NIAID to memorialize this commitment.

2. The terms of this M-CRADA apply to any research project with participation from NIH or CDC where Collaborator Research Material is being used or its effects studied, either alone or in combination with other therapeutics, in preclinical and clinical PrEP research or studies.

3. The NIH or CDC shall promptly report to Collaborator in writing any Subject Invention and any patent applications filed thereon resulting from the research conducted under this M-CRADA that is reported to NIH or CDC's respective technology transfer offices by their respective employees, investigators or any other individual receiving Collaborator Research Materials under the Research Plan or any Project Specific Agreement. NIH and CDC shall require each individual who receives Collaborator Research Material subject to this M-CRADA or who performs any obligation in connection with this M-CRADA to report any Subject Invention promptly to the appropriate technology transfer office after becoming aware of any discovery, invention, conception or reduction to practice related thereto, and each of NIH and CDC shall be responsible for each such individual complying with such reporting requirement. Collaborator agrees to keep all such information provided to Collaborator confidential until the information is published or a patent application is filed, as applicable.

4. If (a) NIH or CDC Generates or acquires any rights to Subject Inventions in connection with any use or other application of Collaborator Research Material as part of the performance of the M-CRADA, or (b) NIH or CDC acquires any Patent Rights that are Improvements to any Existing Patent Rights, NIH and/or CDC, as applicable, hereby grants to Collaborator a worldwide, non-exclusive, royalty-free, sublicensable, transferable, irrevocable license under such Subject Inventions or Improvements to Exploit any product, process or service (the "License"). The License shall be limited to the field of PrEP, except to the extent that the Subject Inventions or Improvements were Generated in connection with Collaborator Research Materials provided by Collaborator, in which case the field is any and all uses. The foregoing License shall be effective on the Generation of such Subject Inventions or Improvements, and shall be sublicensable through one or more tiers to: (y) any Affiliate of Collaborator or (z) any entity in Collaborator's or any Affiliate of Collaborator's supply or distribution chains, including any third-party packager or labeler, intermediary (*e.g.*, wholesaler), healthcare provider (*e.g.*, pharmacist or doctor), or end user (each, an "Authorized Sublicensee"). Without limiting the foregoing, Collaborator may, in its sole discretion, enter into a direct license with any Authorized Sublicensee or transfer the License to any of its Affiliates that is a successor-in-interest of the business unit relevant to any of the Collaborator Research Materials. In the event that NIH or CDC has rights to or acquires from a third party that is not a branch of the United States government (a "Non-Government Third Party") any Subject Inventions or Improvements that would otherwise be subject to the License, NIH or CDC, on behalf of the United States government, will provide a license or sublicense, as applicable, to Collaborator consistent with the License to the maximum extent permitted by the terms of the license or other agreement with such Non-Government Third Party from which such Subject Inventions or Improvements were acquired.

5. As used in this M-CRADA:

a. "Affiliates" means, with respect to any Person, any other Person that is under control of, controlling or under common control with, such entity, from time to time, where "control" and its correlates means the ownership of fifty percent (50%) or more of the equity or voting interests of an entity (or such lesser percentage that is the maximum permitted to be held under applicable law) or otherwise has the ability to direct the management or policies of an entity.

b. "Collaborator Research Materials" means any material that contains: (a) a tenofovir-containing drug or tenofovir prodrug (including tenofovir disoproxil fumarate and tenofovir alafenamide) or (b) a lenacapavir-containing drug or lenacapavir prodrug, in each case, (a) and (b), whether provided by Collaborator or otherwise.

c. "Existing Patent Rights" means U.S. Provisional Patent Application No. 60/764,811 (HHS Ref. No. E-195-2013-0-US-01), U.S. Provisional Patent Application No. 62/876,539 (HHS Ref. No. E-140-2019-0-US-01), U.S. Patent Application No. 11/669,547 (HHS Ref. No. E-195-2013-0-US-02), U.S. Patent Application No. 17/628,170 (HHS Ref. No. E-140-2019-0-US-06), PCT Application No. PCT/US2007/002926 (HHS Ref. No. E-195-2013-0-PCT-03), and PCT Application No. PCT/US2020/015147 (HHS Ref. No. E-140-2019-0-PCT-02), and any Patent Rights that claim priority to any of the foregoing, including any application that is filed as a continuation-in-part of any of the foregoing.

d. "Exploit" means to make, have made, sell, have sold, offer for sale, import, copy, modify, translate, adapt, prepare derivative works of, distribute, publicly display, publicly perform and otherwise use.

e. "Generate" means to create, author, develop, conceive, reduce to practice or otherwise generate.

f. "Improvement" means, with respect to any Patent Rights, any modification, enhancement or other improvement of such Patent Rights.

g. "Patent Rights" means all patents and patent applications (including certificates of invention and applications for certificates of invention), including all divisionals, continuations, substitutions, continuations-in-part, re-examinations, reissues, additions, renewals, revalidations, extensions, registrations, pediatric exclusivity periods and supplemental protection certificates and the like of any such patents and patent applications, and any and all foreign equivalents of the foregoing.

h. "Person" means any individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority, or any other form of entity not specifically listed herein.

i. "PrEP" means pre-exposure prophylaxis.

j. "Subject Invention" means any invention, conceived or first actually reduced to practice under this M-CRADA, that is or may be patentable under 35 U.S.C. § 101 or § 161, protectable under 7 U.S.C. § 2321, or otherwise protectable by other types of U.S. or foreign intellectual property rights.

6. NIH and CDC hereby grant to Collaborator the first right of negotiation of an exclusive license with respect to any Subject Invention. In no event will NIH or CDC offer any license to any third party to such Subject Invention without first offering an exclusive license to Collaborator and negotiating such license in good faith for a period of at least one hundred eighty (180) days. In addition, NIH and CDC shall not offer or agree to any exclusive license to any third party to any Subject Invention if such offer or agreement includes any terms better than those offered to Collaborator for a period of one hundred eighty (180) days after the end of the negotiation with Collaborator therefor. In the event that NIH or CDC has rights to or acquires from a Non-Government Third Party any Subject Invention that would be subject to the negotiation right set forth in this Section 6, NIH or CDC, on behalf of the United States government, will grant such right of first negotiation with respect to such Subject Invention to the maximum extent permitted by the terms of the license or other agreement with such Non-Government Third Party from which such Subject Invention was acquired.

7. Pursuant to 15 U.S.C. § 3710a(b)(1)(A), for Subject Inventions made under this M-CRADA by any NIH employee(s) or CDC employee(s) or jointly by such employee(s) and employees of Collaborator under this M-CRADA, and licensed to Collaborator, Collaborator grants to the United States government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the United States government. In the exercise of such license, the Government shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of 5 U.S.C. § 552(b)(4) or which would be considered as such if it had been obtained from a non-Federal party.

8. Pursuant to 15 U.S.C. § 3710a(b)(2), for a Subject Invention made solely by Collaborator employees under this M-CRADA, the Collaborator grants to the Government, a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government for research or other Government purposes. Unless expressly agreed in writing in an incremental research plan and reflected in the applicable Project Specific Agreement signed by both Parties, the Parties do not envision the Generation of any Subject Inventions by Collaborator hereunder, whether solely or jointly.

9. Pursuant to 15 U.S.C. § 3710a(b)(1)(B), if NIH or CDC grants an exclusive license to a Subject Invention made wholly by NIH or CDC employees or jointly with Collaborator under this M-CRADA, the Government shall retain the right to require Collaborator to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use the invention in Collaborator's licensed field of use on terms that are reasonable under the circumstances; or if the Collaborator fails to grant such a license, to grant the license itself. The exercise of such rights by the Government shall only be in exceptional circumstances and only if the Government determines (i) the action is necessary to meet health or safety needs that are not reasonably satisfied by Collaborator, (ii) the action is necessary to meet requirements for public use specified by Federal regulations, and such requirements are not reasonably satisfied by the Collaborator; or (iii) the Collaborator has failed to comply with an agreement containing provisions described in 15 U.S.C. § 3710a(c)(4)(B). The determination made by the

Government under this paragraph is subject to administrative appeal and judicial review under 35 U.S.C. § 203(b).

10. Any dispute arising under this M-CRADA that is not disposed of by agreement of the NIH or CDC, as applicable, and Collaborator, on the other hand, shall be submitted jointly to the signatories of this M-CRADA. If the signatories are unable to jointly resolve the dispute within thirty (30) days after notification thereof, the Assistant Secretary for Health (or his/her designee or successor) shall propose a resolution. Nothing in this Section 10 shall prevent any Party from pursuing any additional administrative remedies that may be available and, after exhaustion of such administrative remedies, pursuing all available judicial remedies.

11. The illegality or invalidity of any provisions of this M-CRADA shall not impair, affect or invalidate the other provisions of this M-CRADA.

12. Neither this M-CRADA nor any rights or obligations of any Party hereunder shall be assigned or otherwise transferred by either Party without the prior written consent of the other Party.

13. All notices pertaining to or required by this M-CRADA will be in writing, signed by an authorized representative of the notifying Party, and delivered (1) by email with confirmation requested (which shall not constitute notice, and with a copy provided by another means set forth herein) and (2) by first class, registered, or certified mail, or by an express/overnight commercial delivery service, prepaid and properly addressed to the other Party at the address designated on the Contacts Information Page, or to any other address designated in writing by the other Party. Notices will be considered timely if received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Either Party may change its address by notice given to the other Party in the manner set forth above.

14. By entering into this M-CRADA, the Government does not directly or indirectly endorse any product or service that is or will be provided, whether directly or indirectly related to either this M-CRADA or to any Patent Right or other intellectual property license or agreement that implements this M-CRADA by Collaborator, its successors, assignees, or licensees. Collaborator will not in any way state or imply that the Government or any of its organizational units or employees endorses any product or service.

15. Collaborator may unilaterally terminate this M-CRADA at any time by providing written notice to NIH and CDC at least sixty (60) days before the desired termination date. The Parties may terminate this M-CRADA by mutual agreement of the Parties. None of NIH, CDC nor the Government may terminate this M-CRADA for any reason other than by mutual agreement of the Parties. Each of, NIH, CDC and the Government hereby waive any rights of termination in respect of this M-CRADA at common law or otherwise.

16. This M-CRADA constitutes the entire agreement between the Parties concerning the subject matter of this M-CRADA and supersedes any prior understanding or written or oral agreement.

17. The construction, validity, performance and effect of this M-CRADA will be governed by U.S. federal law. If any provision in this M-CRADA conflicts with or is inconsistent with any U.S. federal law or regulation, then the U.S. federal law or regulation will preempt that provision.

18. This M-CRADA shall be effective upon execution by all Parties. The term of this M-CRADA is from the Effective Date through December 31, 2030 (the "Term"), provided that the term of the License shall continue until the expiration of the last-to-expire of the Patent Rights licensed thereunder.

19. The provisions of Articles 5 (for the purpose of interpreting this M-CRADA), 10 through 14, and 16 through 19 shall survive the termination of this M-CRADA.

SIGNATURE PAGE

ACCEPTED AND AGREED

BY EXECUTING THIS M-CRADA, EACH PARTY REPRESENTS THAT ALL STATEMENTS MADE HEREIN ARE TRUE, COMPLETE, AND ACCURATE TO THE BEST OF ITS KNOWLEDGE. COLLABORATOR ACKNOWLEDGES THAT IT MAY BE SUBJECT TO CRIMINAL, CIVIL, OR ADMINISTRATIVE PENALTIES FOR KNOWINGLY MAKING A FALSE, FICTITIOUS, OR FRAUDULENT STATEMENT OR CLAIM.

FOR NIH:

Lawrence A. Tabak -S Digitally signed by Lawrence A. Tabak -S
Date: 2025.01.14 19:55:54 -05'00'

Signature Date

Lawrence A. Tabak, D.D.S., Ph.D.
Typed Name

Principal Deputy Director, National Institutes of Health
Title

FOR CDC:

Signature | Date

Debra Houry, M.D., M.P.H.
Typed Name

Deputy Director for Program and Science/Chief Medical Officer
Centers for Disease Control and Prevention
Title

FOR COLLABORATOR:

Deb Telman | 1/14/2025

Signature | Date

Deborah H. Telman
Typed Name

Executive Vice President of Corporate Affairs & General Counsel
Title

CONTACTS PAGE

M-CRADA Notices

For NIH:

Director, Technology Transfer and Intellectual Property Office
Attn: M-CRADA C-026-2025
National Institute of Allergy and Infectious Diseases
Suite 2G, MSC 9804
5601 Fishers Lane
Rockville, MD 20852
Tel: 301-496-2644
Fax: 240-627-3117
Email: NIAIDInnovation@mail.nih.gov

with a copy to

NIH Office of Technology Transfer
6701 Rockledge Drive, Suite 700
MSC 7788
Bethesda, MD 20892
LicenseNotices_Reports@mail.nih.gov

For CDC:

Technology Transfer Office
Office of Science
ATTN: Legal Notice CDC Ref: M-CRADA D-141-25
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Mailstop H21-8
Atlanta, Georgia 30329-4027
Email: TTO@CDC.GOV

with a copy to

TTD@CDC.GOV

For Collaborator:

Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, California 94404, USA
Attention: General Counsel
generalcounsel@gilead.com

with a copy to

Wilmer Cutler Pickering Hale and Dorr LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
Attention: David B. Bassett

David.Bassett@wilmerhale.com

and

Wilmer Cutler Pickering Hale and Dorr LLP
2100 Pennsylvania Avenue NW
Washington, DC 20037
Attention: Ronald C. Machen
Ronald.Machen@wilmerhale.com

Patenting and Licensing

For NIH:

Director, Technology Transfer and Intellectual Property Office
Attn: M-CRADA C-026-2025
National Institute of Allergy and Infectious Diseases
Suite 2G, MSC 9804
5601 Fishers Lane
Rockville, MD 20852
Tel: 301-496-2644
Fax: 240-627-3117
Email: NIAIDInnovation@mail.nih.gov

with a copy to

NIH Office of Technology Transfer
6701 Rockledge Drive, Suite 700
MSC 7788
Bethesda, MD 20892
LicenseNotices_Reports@mail.nih.gov

For CDC:

Director, Technology Transfer and Intellectual Property Office
Attn: M-CRADA C-026-2025
National Institute of Allergy and Infectious Diseases
Suite 2G, MSC 9804
5601 Fishers Lane
Rockville, MD 20852
Tel: 301-496-2644
Fax: 240-627-3117
Email: NIAIDInnovation@mail.nih.gov

with a copy to

TTO@CDC.GOV
TTD@CDC.GOV

For Collaborator:

Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, California 94404, USA
Attention: General Counsel
generalcounsel@gilead.com

with a copy to

Wilmer Cutler Pickering Hale and Dorr LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007

Attention: David B. Bassett
David.Bassett@wilmerhale.com

and

Wilmer Cutler Pickering Hale and Dorr LLP
2100 Pennsylvania Avenue NW
Washington, DC 20037
Attention: Ronald C. Machen
Ronald.Machen@wilmerhale.com

Delivery of Materials Identified in Article 1

To be set forth in each Project Specific Agreement.

SUMMARY PAGE

EITHER PARTY MAY, WITHOUT FURTHER CONSULTATION OR PERMISSION, RELEASE THIS SUMMARY PAGE TO THE PUBLIC.

TITLE OF M-CRADA: PrEP Research or Studies Using Tenofovir-Containing Drugs or Tenofovir Prodrug (including tenofovir disoproxil fumarate and tenofovir alafenamide) or Lenacapavir-Containing Drugs or Lenacapavir Prodrugs

TERM OF M-CRADA: Expires December 31, 2030.

ABSTRACT OF THE MASTER RESEARCH PLAN:

NIH and CDC will conduct preclinical and clinical research regarding the use of material that contains: (a) a tenofovir-containing drug or tenofovir prodrug (including tenofovir disoproxil fumarate and tenofovir alafenamide) or (b) a lenacapavir-containing drug or lenacapavir prodrug, either alone or in combination with other therapeutics, for use in PrEP research or studies. From time to time, as reasonably requested by NIH or CDC, Gilead will supply the materials in the amounts and for the purposes specified in one or more project specific agreements consistent with the M-CRADA and agreed to by the Parties.

APPENDIX A

MASTER RESEARCH PLAN

NIH and CDC will conduct preclinical and clinical research regarding the use of the Collaborator Research Material(s), either alone or in combination with other therapeutics, for use in PrEP research or studies. Collaborator agrees to consider in good faith whether to provide the Collaborator Research Materials upon written request of NIH or CDC, as set forth in a proposed Project Specific Agreement.