



**U.S. NON-INTERVENTIONAL CLINICAL STUDY AGREEMENT
FOR PROTOCOL GS-US-528-7614**

This Clinical Study Agreement (“Agreement”) is entered into as of the date of last signature (the **“Effective Date”**) by and between **Cook County, through its Cook County Health & Hospitals System d/b/a Cook County Health** with an address at 1950 W. Polk St., Suite 9816 Street Chicago, IL 60612 (the **“Institution”**) and **Gilead Sciences, Inc.**, a Delaware corporation with headquarters located at 333 Lakeside Drive, Foster City, California, 94404, U.S.A. (together with its affiliates and subsidiaries **“Gilead”**), in connection with a clinical study conducted pursuant to Protocol GS-528-7614, **“Pioneering Research to Optimize Pre-exposure Prophylaxis (PrEP) Expansion with Lenacapavir (LEN)”** (together with any amendments thereto, which are incorporated herein by reference, the **“Protocol”**) (the **“Study”**), at Institution (**“Study Site”**). The Study will be conducted under the immediate supervision of **Monica Mercon, MD** with National Provider Identifier (NPI) Number **1437411659** (the **“Investigator”**). PPD Investigator Services LLC (the **“CRO”**) is serving as Gilead's contract research organization for the Study. Hereafter, Gilead and Institution are sometimes referred to individually as **“Party”** or collectively as the **“Parties.”** The Parties agree as follows:

1. OBLIGATIONS FOR THE CONDUCT OF THE STUDY

1.1 Compensation. Gilead will pay the Institution’s payee as set forth in the Budget and Payment Schedule attached hereto as **Exhibit A** and incorporated herein by reference.

- a) The Parties agree that the compensation paid under this Agreement constitutes the fair market value of the performance of Study-related activities to be provided hereunder and is unrelated to the volume or value of any referrals or other business otherwise generated between the Parties.
- b) No amounts paid under this Agreement are intended to be for, nor shall they be construed as, an offer or payment made in exchange for any explicit or implicit agreement to purchase, prescribe, recommend, or provide a favorable status for, any Gilead product or service.
- c) Institution will not seek or accept from Study subjects or third-party payors, including any government entity or insurance company, compensation for any Study related material or service provided or paid for by Gilead.
- d) Institution represents and certifies that it will conduct the Study in full compliance with all applicable healthcare billing, coverage and reimbursement laws, rules, regulations, and guidance, including, but not limited to, legal authorities related to billing Medicare, Medicaid, and other federal health care programs for items and services provided to Study subjects. The Institution represents that it has the sole responsibility to determine whether it is appropriate to bill payors for items and services provided to Study subjects, and that it is solely responsible for obtaining any necessary prior approvals from payors before billing payors for items and services provided to Study subjects.
- e) If Gilead requires Investigator and Study Personnel (as defined below) to attend an investigator meeting for the Study, Gilead will arrange and pay for the expenses directly for travel, accommodation, and meals in connection with such attendance. Such covered expenses may be publicly reportable. No compensation will be paid in connection with attending the investigator meeting.

1.2 Study Conduct. Institution will conduct the Study at the Study Site in strict compliance with (i) the Protocol; (ii) the obligations of Institution under this Agreement; (iii) all applicable laws, rules, regulations and guidance, including, without limitation, the Federal Food, Drug and Cosmetic Act, as amended, and regulations and guidelines of the U.S. Food and Drug Administration (the “**FDA**”) and all applicable anti-corruption, anti-kickback, and fraud and abuse statutes; (iv) good clinical practice requirements as may be published by the FDA from time to time (“**GCP**”); (v) International Conference on Harmonised Tripartate Guidelines for Good Clinical Practice to the extent adopted by the FDA (“**ICH-GCP**”); and (iv) generally accepted treatment standards of the medical profession. Institution will not deviate from the Protocol without the advance written consent of Gilead, unless in the good medical judgment of Investigator, a deviation is necessary to protect the safety of the Trial subjects due to emergent or urgent medical conditions, in which case Investigator or Institution shall notify Gilead orally of such deviation and the justification for it within twenty-four (24) hours after its occurrence and provide a written report to Gilead within five (5) business days after the occurrence of such deviation. .

1.3 Compliance of Investigator. Institution represents that Investigator is an employee of Institution and has signed the signature page of the Protocol and this Agreement, and certifies that the Investigator will comply with all terms of the Protocol and this Agreement.

1.4 Debarment, Restriction, or Inability of Investigator. Institution will promptly notify Gilead in writing if during the course of the Study, Investigator: (i) is debarred or disqualified by his/her professional governing body, any regulatory authority, including the FDA, or other government authority; (ii) receives notification of any restriction on his/ her clinical privileges at Institution; (iii) is sanctioned by state, federal or international regulatory authorities or other governmental authorities; (iv) terminates or has been terminated from his/her employment or other contractual relationship with the Institution; or (v) otherwise becomes unfit, unable or unwilling to fulfill his/her obligations under this Agreement. In the event of any of (i-iii) and (v), if the Investigator is still employed by the Institution, Institution will ensure that the original Investigator will continue to comply with the terms of this Agreement and in the event of (iv) Institution will ensure that the original Investigator is informed of his/her obligations to continue to comply with the terms of this Agreement, including the confidentiality obligations set forth in Section 4 and the intellectual property obligations set forth in Section 6. If requested by Gilead, Institution will cooperate to find a suitable replacement investigator or transition the Study to another institution in a timely manner so as not to interrupt the Study.

1.5 IRB Approvals and Informed Consent Form. Prior to the commencement of the Study at the Study Site, Institution will obtain approval for the Study, including approval of the Protocol informed consent form and, if applicable, pediatric consent form (collectively, “**ICF**”), and any amendments to any of the foregoing, from the applicable Institutional Review Board (“**IRB**”) in accordance with applicable state and federal laws, rules and regulations. Institution or Investigator will obtain from each individual (or such individual’s legal representative) who is to be screened for participation in the Study, a properly executed ICF, as approved by Gilead and the IRB before such individual is allowed to be screened for participation in the Study. Gilead, Institution and/or Investigator will ensure that the ICF complies in form and content with applicable laws, regulations and guidance including GCP, ICH-GCP, and laws governing data protection and privacy, as well as all relevant terms of the Protocol.] Institution or Investigator will promptly supply Gilead or CRO with appropriate evidence of IRB approval, a copy of the IRB-approved ICF, and any amendments to the ICF later approved by the IRB prior to its use by Institution. Any proposed deviations by Institution from Gilead’s model ICF language must be approved by Gilead in advance of any use with patients in the Study. Breach of this Section 1.5 will constitute a material breach of this Agreement.

1.6 HIPAA Authorization. Institution and Investigator shall ensure that the ICF

obtained for each individual who is to participate in the Study includes the express written authorization of such individual or such individual's legal representative for the disclosure by Institution to Gilead, applicable regulatory authorities and the employees, agents, and independent contractors of Gilead and its affiliates, of such individual's Protected Health Information (as such term is defined in 45 CFR § 160.103) pursuant to the U.S. Health Insurance Portability and Accountability Act of 1996 and regulations, laws, and guidelines related thereto (collectively, "HIPAA"). In the alternative, the Parties will ensure that a properly executed written authorization (the "Authorization") is obtained from each such individual or such individual's legal representative to document the Study patient's express written authorization for the disclosure by Institution to Gilead, applicable regulatory authorities and Gilead's employees, agents, and independent contractors of such individual's Protected Health Information pursuant to HIPAA. Each Party will cooperate in the amendment of the ICF, Authorization or other documents as may be necessary, from time to time, to comply with HIPAA to the extent HIPAA applies to such Party, and to ensure that the Study Results (as defined below) may be used by Gilead for the purposes contemplated under this Agreement. Gilead will be entitled to review and revise as appropriate such Authorization or other document or any modification thereof prior to use by Institution, patient to subsequent approval by the IRB, as applicable.

1.7 FDA Form 1572; Financial Disclosures. Prior to the commencement of the Trial at Institution, Investigator will complete, sign and deliver to Gilead the FDA Form 1572 as described in 21 CFR §312.53. In addition, prior to the commencement of the Trial at Institution, the Institution and Investigator shall ensure that the Investigator and each individual listed on the FDA Form 1572 provides to Gilead a signed financial disclosure form disclosing either the existence or absence of any and all financial interests and arrangements identified in 21 CFR § 54.4(a) so that Gilead and its affiliates are able to submit complete and accurate certifications or disclosure statements as required by 21 CFR § 54.4(a). In addition, during the term of this Agreement and for one (1) year after the completion or termination of the Trial, Institution shall ensure that all individuals listed on the FDA Form 1572 promptly notify Gilead of any changes or updates to the information contained in the signed financial disclosure forms submitted by such individuals.

Material Safety Information:

1.7 Safety Reporting. Institution or Investigator will report all serious adverse events, special situation reports and other safety concerns as specified in the Protocol and in accordance with applicable laws, rules and regulations, including, but not limited to FDA regulations. For the avoidance of doubt, each of the Investigator and the Institution will provide all reasonable assistance to Gilead to allow Gilead to comply with all applicable requirements.

1.8 Study Personnel Personal Data. Personal data provided by Institution, Investigator, and Trial Personnel relating to the Institution, Investigator, and Study Personnel (such as names, address, phone numbers, email addresses, CVs, etc.) will be processed and held on one or more databases. Such data may be used for the purposes of: (i) the conduct of the Study; (ii) verification by governmental or regulatory agencies, Gilead, CRO, their agents and affiliates; (iii) compliance with legal and regulatory requirements; (iv) publication on www.clinicaltrials.gov and websites and databases that serve a comparable purpose; and (v) storage in databases to facilitate the selection of investigators for future clinical Studies. Personal data may be disclosed or transferred to Gilead's affiliates, subsidiaries, representatives, and contractors working on behalf of Gilead, and to regulatory authorities across the world. The Institution shall notify Investigator and Study Personnel of Gilead's use of personal data set forth in this Section.

2. STUDY RECORDS RETENTION; INSPECTION ; EQUIPMENT

2.1 Gilead's products.

Records Maintenance and Retention. Institution will maintain adequate and accurate records relating to disposition of the Study Drug and the performance of all required Protocol procedures on Study subjects, including but not limited to, written source documents, medical records, charts pertaining to individual Study subjects, "Case Report Forms" ("CRFs"), accounting records, notes, reports, and data. Institution will retain these documents for the longer of: (i) twenty-five (25) years after completion or earlier termination of the Trial at Institution; or (ii) such other minimum retention period requirements as required by applicable law. Institution will notify Gilead in writing prior as provided under Section 9.9 of this Agreement to destruction of any Study-related records and, if requested by Gilead, shall transfer such records to Gilead at Gilead's expense. If Gilead does not respond to Institution within sixty (60) days, Institution may proceed with record destruction. For the avoidance of doubt, Institution remains the owner of patient medical records and other source documents provided under this Agreement.

2.2 Inspection and Assistance with FDA/Other Regulatory Matters.

At mutually agreeable times, agreement to which may not be reasonably withheld by Institution and upon reasonable notice which shall be no less than forty-eight (48) hours notice to Institution's Director of Clinical Research Office, Gilead and its respective appointed representatives shall have the right to inspect, audit, and monitor the Study Site, Institution's facilities, and all records described in Section 2.3 solely for the purpose of the Study. Each of the Institution, Study Site and Investigator will cooperate with Gilead and its appointed representatives with respect to such inspections, audits and monitoring visits. Any access to Institution facilities, medical records, and source documents granted to Gilead will be in accordance with Institution guidelines to the extent (i) Institution provides a copy of the guidelines in advance of such access and (ii) such guidelines don't conflict with GCP (to the extent adopted by FDA regulations), applicable law, the informed consent form or the terms of this Agreement. Any copies of material related to the audit or inspected provided by CCH to Gilead will be redacted to protect third-party confidentiality. Institution reserves the right to prohibit any person from entering its or other Cook County facilities for any reason. When requested by Institution, Gilead will provide documentation evidencing such personnel assigned by Gilead to be onsite at Institution or other Cook County facilities will have had a fingerprint-based background check, drug and TB tests, and designated immunizations and vaccinations. Gilead shall bear the costs of all such checks, tests, immunizations, and vaccinations.

Institution or Investigator will notify Gilead promptly upon receiving notice of, and will reasonably cooperate with Gilead on, any impending inspection or other action related to the Study by the FDA or other governmental or regulatory authority. Unless otherwise prohibited by applicable law or order, Institution will promptly provide Gilead with a copy of any documentation relating to the Study received from or sent to the FDA or any other regulatory authority related to the Study.

2.3 Equipment. Either Gilead, or CRO, or other vendor acting on Gilead's behalf, may provide the Institution and Investigator, equipment for the conduct of the Trial (the "Equipment") at Gilead's expense. Unless otherwise agreed by Gilead in writing, the Equipment will be used only by the Investigator and Trial Personnel solely for the purposes of the Trial. The Equipment is and shall remain the sole property of CRO or Gilead, or the vendor providing the Equipment. The Equipment will only be used in the manner intended and only as described in written directions provided by the manufacturer and/or CRO, Gilead, or the vendor. The Institution will take reasonable care in the use and secure storage of the Equipment. Except as otherwise provided in a separate agreement between the providing vendor and the Institution, Institution shall: (i) at Gilead's expense, maintain the Equipment

in good working order; (ii) promptly notify the provider of the Equipment upon becoming aware of the need for Equipment maintenance or repair; and (iii) at the completion of the Trial or at Gilead's request, return to CRO, Gilead, or the providing vendor, as applicable and at Gilead's expense monitoring visits.

At Gilead's request and expense, Institution and/or Investigator, as appropriate, will assist Gilead in the preparation and submission of investigational new drug applications, new drug applications, and any other pre-market applications relating to the Trial as may be required by the FDA or other regulatory authorities, and will attend meetings with such regulatory authorities regarding such applications to the extent such meetings are at mutually agreeable times.

3. REPRESENTATIONS AND CERTIFICATIONS

3.1 Institution represents and certifies that it has the legal authority to enter into this Agreement and that to the best of its knowledge, after reasonable due diligence, the terms of this Agreement are not in conflict with any other agreements to which it is legally bound. Institution will not, and shall require that Investigator will not, enter into any agreement or engage in any activities that would materially impair its or his/her ability to complete the Study in accordance with this Agreement and the Protocol.

3.2 Institution represents and certifies that the Investigator is fully qualified as a medical practitioner under applicable state and federal laws and regulations and is fit to perform his/her obligations under this Agreement. Institution represents and certifies that it will not, in the course of performing the Study, use in any capacity the services of any person or entity who has been debarred, disqualified as an investigator, or restricted by the FDA pursuant to the Generic Drug Enforcement Act of 1992 or any other equivalent or successor statutes, rules or regulations. Institution represents and certifies that none of Institution, Investigator, and any of the individuals or entities providing services for the Study on behalf of Institution (collectively, the "**Study Personnel**"), are debarred, disqualified, restricted, or banned from conducting clinical trials. Institution will notify Gilead promptly if any Study Personnel becomes disqualified, debarred or restricted.

3.3 Anti-Corruption. Institution represents and certifies that neither the Institution, nor to Institution's knowledge any of its affiliates, nor any of their respective directors, officers, employees or agents (all of the foregoing, including affiliates collectively, "**Institution Representatives**") has taken any action that would result in a violation by such persons of any applicable anti-bribery or anti-corruption laws, rules or regulations (collectively the "**Anti-Corruption Laws**"). Institution represents and certifies that the Institution and Institution Representatives have conducted and will conduct their businesses in compliance with the Anti-Corruption Laws, including refraining from making any payments or providing anything of value, directly or indirectly, to improperly influence a third party or improperly gain a business advantage. Institution represents and certifies that Institution has and will have necessary procedures in place to prevent bribery and corrupt conduct by Institution Representatives and that Institution will keep accurate books, records, and accounts in connection to the Study. Institution also agrees that Gilead shall have the right, from time to time, and not more than once per year, upon written notice to Institution, to conduct an audit of Institution's policies, books, records and accounts relating to the Study to verify compliance with the provisions of this Agreement subject to the requirements of Section 2.4(a) herein. Institution agrees to cooperate fully with such audit. Without limiting any other remedies at law or at equity, Gilead may, at Gilead's sole discretion, terminate this Agreement, for any violation of the Anti-Corruption Laws upon written notice to Institution.

3.4 Institution represents and certifies that Investigator and all other Study Personnel

are, or prior to the commencement of the Study, will be contractually obliged to convey to Institution all title and interest to Study Results and Study Inventions as defined below. In addition, Institution shall ensure that all Study Personnel comply with the provisions of this Agreement.

Gilead certifies that (a) it is not debarred under Subsections 306(a) or (b) of the Federal Food, Drug, and Cosmetic Act and that it will promptly notify Institution if it becomes debarred during the term of this Agreement. Gilead further certifies that it is not excluded from any federal health care program, including but not limited to Medicare and Medicaid and that it will promptly notify Institution if it becomes excluded during the term of this Agreement.

4. CONFIDENTIALITY

4.1 Institution will (and will cause Investigator and Study Personnel to) keep confidential and not disclose to third parties all information provided by or on behalf of Gilead or CRO or that is generated, discovered, or obtained by any Party Gilead will endeavor to identify as confidential at the time of disclosure any Confidential Information disclosed in written oral or tangible form to the Institution or Investigator.” Study Results, Study Inventions and information related thereto (“**Confidential Information**”). Institution will use, and will cause Study Personnel, including Investigator, to use, Confidential Information only for purposes of the Study. The obligations of this Section 4 will survive expiration or termination of this Agreement for a period of five5years. Confidential Information will not include information that:

is or becomes publicly available through no fault of Investigator or Institution;

was known to Investigator or Institution without obligation of confidentiality prior to receiving it either directly or indirectly from Gilead under this Agreement, as demonstrated by written records predating the date it was learned by Investigator or Institution from Gilead;

is disclosed to Investigator or Institution by a third party without violation of law or any obligation of confidentiality; or

can be shown by written records of Institution or Investigator to have been independently developed by Institution or Investigator without reference to or reliance upon any Confidential Information.

4.2 Notwithstanding any other provision of this Agreement, Institution and Investigator may disclose Confidential Information to the extent required:

to comply with an applicable governmental law, rule, regulation or order, after prompt notice to Gilead and provided that Investigator and Institution cooperate with Gilead’s efforts to limit such disclosure by appropriate legal means;

to protect any Study subject’s safety or provide appropriate medical care for any Trial subject, or to prevent a public health emergency with prompt notice to Gilead;

for purposes of insurance or reimbursement by a third party payor for medical treatment of a Study subject related to the procedures included in the Protocol.

4.3 Section 4 does not limit Institution’s or Investigator’s rights or obligations under Sections: 1.5 (IRB Approvals and Informed Consent Form); 2.4 (Inspection and Assistance with

FDA/Other Regulatory Matters); 5 (Publication); 9.1 (Publicity); or 9.2 (Relationship).

4.4 Return of Confidential Information. Upon either (i) the completion of the Study or termination of this Agreement; or (ii) Gilead's request for any reason, Institution will (x) immediately cease all use of all Confidential Information, and (y) promptly either return to Gilead, or if instructed by Gilead, destroy all Confidential Information, including any copies, extracts, summaries, or derivative works thereof, and certify in writing to Gilead the completion of such return and/or destruction; provided, however, that Institution may retain one (1) copy of Confidential Information in its legal archives solely for the purpose of monitoring its surviving obligations under this Agreement.

4.5 Injunctive Relief. Institution acknowledges that any actual or threatened breach of this Section 4 may cause Gilead immediate and irreparable harm that cannot be adequately compensated by monetary damages, and it therefore agrees that Gilead may not be required to demonstrate irreparable harm in order to seek or obtain injunctive relief for actual or threatened breach of this Agreement. In addition to any injunctive relief, Gilead may seek any other remedies available to it at law or in equity.

5. PUBLICATION

5.1 Institution and Investigator may publish or present the results of the Study generated by Institution and Investigator (the "**Study Results**") either: (i) with the advance written consent of Gilead; or (ii) two (2) years after the completion of the Study at all participating institutions (each, a "**Publication**"). Investigator will submit all proposed Publications along with the name of the intended scientific journal, forum or conference, to Gilead prior to submission of the Publication thirty (30) days prior for manuscripts and fifteen (15) days for abstracts and oral presentations). Institution and Investigator will delete references to Gilead's Confidential Information in any paper or presentation and, at Gilead's request, delay such Publication for up to forty-five (45) days in order to permit Gilead to obtain appropriate intellectual property protection on any Confidential Information contained in the Publication. Gilead may not request the deletion of (a) Study Results or (b) a description of methodology which is reasonably necessary for acceptance by academic journals.

5.2 Other than as permitted in Section 5.1, the use of Gilead's name, or the names of Gilead's affiliates or employees, in any publication is governed by Section 9.1. Gilead agrees to ensure that the Study is registered under applicable law.

6. STUDY RESULTS AND INVENTIONS

6.1 Gilead owns all data, Study Results, Confidential Information, and CRFs. Gilead hereby grants to the Institution a non-exclusive, non-transferable, non-sublicensable right to use the Study Results solely for its own internal, non-commercial research, patient care, and educational purposes subject to the terms of Section 5.1.

6.2 All inventions, ideas, methods, works of authorship excluding Publications, know-how, or discoveries that are made, conceived, or reduced to practice by Institution, Investigator or Study Personnel: in the direct performance of the Study that incorporate or use Confidential Information, or (ii) that are directly related to the Compound, and in each case together with all intellectual property rights relating thereto (collectively, "**Study Inventions**"), will be the sole and exclusive property of Gilead or its designee. Institution or Investigator will promptly disclose all Study Inventions to Gilead in writing. Institution hereby assigns, and will cause Investigator and Study Personnel to assign to Institution, which will then assign to Gilead, all right, title and interest in all Study Inventions to Gilead or its designee. At Gilead's request and expense, Institution shall take, and shall cause Investigator and

Study Personnel to take, all additional actions as Gilead deems necessary to perfect the interest of Gilead or its designee in Study Inventions or to obtain patents or otherwise protect the interest of Gilead or its designee in Study Inventions.

7. INDEMNIFICATION

7.1 Gilead will indemnify, defend and hold harmless Institution and its affiliated entities and their respective trustees, directors, employees, officers, agents, including Investigator (“**Institution Indemnitees**”) for any losses, costs, expenses, liabilities, or damages finally awarded by court order or finally paid in settlement or judgment (including reasonable attorney’s fees) (“**Losses**”) incurred as a result of third party claims, suits, demands, actions or proceedings (“**Third Party Claims**”) brought against an Institution Indemnitee, which arise out of: (i) Institution’s performance of its obligations under this Agreement in accordance with the Protocol ; (ii) Gilead’s use of the Study Results, (iii) the design or manufacture of the Compound, or (iv) Gilead’s negligence, willful misconduct, or breach of this Agreement (including any representations or warranties by Gilead) or applicable law.

7.2 Gilead will not indemnify, defend or hold harmless Institution Indemnitees for Losses to the extent such Losses arise out of: (i) any failure of an Institution Indemnitee to conduct the Study in accordance with the Protocol, the terms of this Agreement or any applicable law, rule, guidance, or regulation; (ii) the negligence or willful misconduct on the part of any Institution Indemnitee; or (iii) a breach of any of the Institution’s representations, warranties or obligations under this Agreement.

7.3 Notice of Indemnification Claim. Institution will give notice to Gilead as promptly as practicable of any Third Party Claims made or commenced against any Institution Indemnitees of which Institution becomes aware.

Notice of Election. Institution will have the option to either: (a) undertake the defense of the Institution Indemnitees, in which case Institution will provide qualified attorneys, consultants and other appropriate professionals, reasonably acceptable to Institution, to represent the interests of the Institution Indemnitees; or (b) authorize the Institution Indemnitees to undertake its own defense, in which case the Institution Indemnitees will provide its own qualified attorneys, consultants and other appropriate professionals to represent its interests. Institution will provide notice to Gilead of the option Institution elects no later than thirty (30) days following the date of Institution’s notice to Gilead of a Third Party Claim. Under either option that Institution elects, Gilead will be responsible for and pay the reasonable fees and expenses of such attorneys, consultants and other professionals in the investigation, trial and defense of the Third Party Claim and any appeal arising therefrom.

Institution Election to Defend. If Gilead undertakes the defense of the Institution Indemnitees, the Institution Indemnitees will cooperate, at Gilead’s cost and expense, in all reasonable respects with Gilead and its attorneys in the investigation, trial and defense of the Third Party Claim and any appeal arising therefrom; provided the Institution Indemnitees may, at its own cost and expense, participate through its attorneys or otherwise in such investigation, trial and defense of the Third party Claim and any appeal arising therefrom. Gilead will not admit liability or settle any Third Party Claim that involves a remedy other than the payment of money without the Institution Indemnitee’s prior written consent.

Failure to Notify or Otherwise Perform. Any failure by Institution or an Institution Indemnitees to provide notice of Third Party Claim to or cooperate with Gilead, as contemplated in this Section, will reduce Gilead’s indemnification obligations only to the extent Gilead is prejudiced thereby. If Gilead fails to notify the Institution Indemnitees of Gilead’s election under this Section or otherwise fails to acknowledge its obligation to indemnify the Institution Indemnitees no later than ten (10) days following the date of Institution’s notice to Sponsor of a Indemnification Claim, the Institution

Indemnitees need not obtain Gilead's written consent prior to engaging its own qualified attorneys, consultants and other appropriate professionals to represent its interests and undertake its investigation and defense prior to admitting liability or settling the Indemnification Claim, all at Gilead's obligation to pay the reasonable fees and expenses and other losses, including any settlement payment or judgment amounts, that the Institution Indemnitees may incur.

8. INSURANCE AND PATIENT INJURY

8.1 Gilead will maintain in effect appropriate levels of insurance or self-insurance for the duration of the Study in amounts sufficient to meet its liability obligations under this Agreement, but not less than \$3,000,000 per occurrence and \$5,000,000 aggregate. Institution will maintain in effect appropriate levels of insurance or self-insurance for the duration of the Study in amounts sufficient to meet its liability obligations under this Agreement. Institution or Investigator will provide certificates of insurance to Gilead upon reasonable request. Institution will notify Gilead in writing within twenty (20) days of any notice of cancellation or non-renewal of, or material change in, its insurance coverage that would render Institution in breach of its obligations under this Section 8.1. Each Party's insurance coverage will comply with applicable laws, rules, regulations and insurance guidelines.

8.2

Institution will provide medical treatment to Study subjects who suffer an adverse reaction, illness or injury during the Trial. Gilead will reimburse Institution for the reasonable and necessary costs of providing such medical treatment, including diagnosis thereof, to the extent the adverse reaction, illness or injury was directly caused by the use of the Compound in accordance with the Protocol or procedures performed in accordance with the Protocol. In the event diagnostic procedures are required to determine the etiology of the subject's adverse reaction or injury, Gilead shall pay the reasonable expense of such diagnostic work-up without regard to the final diagnosis, but Gilead shall not be responsible for expenses connected with the subsequent treatment of the subject if the work-up establishes that the subject's adverse reaction or injury is not related to the administration of the Compound or procedures required by the Protocol. Notwithstanding the foregoing, Gilead's obligation to reimburse Institution will not apply to the extent such adverse reaction, illness, or injury is caused by: (i) the negligence or misconduct of Institution, Investigator or Study Personnel; (ii) a failure to adhere to the Protocol, other written instructions provided by Gilead, or applicable laws, rules, guidance, or regulations; provided, however, that a deviation from the Protocol in accordance with Section 1.2 shall not be deemed to be a failure to adhere to the Protocol; or (iii) the natural progression of a pre-existing medical condition or underlying disease of the Study subject, unless such progression is a direct result of participation in the Study or administration of the Compound in accordance with the Protocol.

If at any time during the Study, Institution, Investigator or Gilead reasonably concludes that any Study subject should immediately be withdrawn from participation in the Study, the Parties will cooperate to safely withdraw such Trial subject.

9. GENERAL

9.1 Publicity. Neither Party will use the name of the other Party or the other Party's employees or any of their trademarks in any advertising, sales promotional material, or press release without the other Party's prior written approval, except to the extent such disclosure is reasonably necessary for: (i) regulatory filings, including filings with the U.S. Securities and Exchange Commission or the FDA (or any equivalent oversight body in a country other than the United States); (ii) prosecuting or defending litigation; and (iii) complying with applicable laws, rules, and regulations. Notwithstanding

the foregoing, Gilead may, without prior consent, publicly disclose information about Institution and Investigator as required by applicable law, including, but not limited to identifying Institution as the entity that is conducting the Study, Investigator as conducting the Study at Institution, and the amount of funding provided and expenses covered in connection with the Study. Institution and Investigator may, without prior consent, disclose their participation in the Study (including Gilead's name, the name of the Study and Protocol number). Notwithstanding the foregoing, Institution may acknowledge the existence of this Agreement and may disclose Gilead as the source of funding for the Trial, aggregate funding amount, as well as the Protocol title, as necessary to comply with regulatory, academic, and State reporting requirements.

9.3 Relationship. For the purposes of this Agreement, the Parties are independent contractors and nothing contained in this Agreement will be construed to place them in the relationship of partners, principal and agent, employer and employee or joint venturers. Neither Party will have the power or right to bind or obligate the other Party, or hold itself out as having such authority.

9.4 Term. Unless terminated earlier by written notice of one Party to the other in accordance with Section 9.4, this Agreement will expire upon the later of the date on which: (i) Gilead has received all completed CRFs from Institution; (ii) Institution has resolved all data clarification queries, and submitted the closeout reports to the IRB and to Gilead to Gilead's satisfaction; (iii) all Study Site closeout activities have been completed; and (iv) Gilead has made all payments and reimbursements and collected all refunds due under this Agreement.

9.5 Termination. Either Party may terminate this Agreement upon 30 days' written notice to the other Party or immediately if (i) either Party reasonably believes termination is necessary to protect the health, safety or welfare of the Trial subjects or (ii) Gilead is debarred, excluded, suspended, or otherwise determined to be ineligible to participate in federal health care programs (collectively, "Ineligible"). Accordingly, Gilead shall provide Institution with notice if Gilead becomes Ineligible.

9.6 Surviving Terms. In the event of expiration of this Agreement under Section 9.4 or termination of this Agreement under Section 9.5, the rights and obligations in the following Sections shall survive: 1.7, 2, 4, 5, 6, 7, 8.1, and 9, and will remain in full force and effect following termination or expiration of this Agreement.

9.7 Entire Agreement; Amendments. This Agreement, including any attachments referenced herein and the Protocol constitute the entire, final, complete and exclusive understanding of Gilead and Institution concerning the Study. If there is a conflict between the terms of this Agreement and the Protocol, the terms of this Agreement will govern, except for conflicts related to matters of medicine, science, safety and conduct of the Study which will be governed by the terms of the Protocol. This Agreement may be executed in counterparts. No changes, amendments or alterations will be effective unless in writing and signed by both Parties. No waiver, expressed or implied, will be a continuing or subsequent waiver of the particular right or obligation. Any purported assignment or delegation by Institution or Investigator of this Agreement or their obligations under this Agreement will be void without Gilead's advance written consent. Gilead reserves the right to assign or transfer this Agreement or any of the rights or obligations under this Agreement, provided that the acquiring party assumes all obligations of Gilead herein. Gilead reserves the right to assign or transfer this Agreement or any of its rights or obligations under this Agreement and shall use reasonable efforts to provide notice of such assignment to Institution..

9.8 Severability. Any provision in this Agreement determined by proper judicial authority to be invalid or unenforceable will be revised by agreement of the Parties to the extent necessary

to avoid the remainder of the Agreement being invalid or unenforceable.

9.9 Notice. Any notice or consent required to be given under this Agreement must be in writing and sent to the other Party either: (i) by certified mail, return receipt requested, which will be deemed delivered three (3) days after deposit with the U.S. Postal Service; (ii) via a nationally recognized delivery service with guaranteed next business day delivery, which will be deemed delivered one (1) day after deposit with such carrier; or (iii) by confirmed facsimile transmission or PDF document via email which will be deemed delivered at the beginning of the next regular business day following successful transmission. Notices will include reference to the Study Protocol number and be forwarded to the following:

If to Institution:

Attention: _____

Tel (for courier use): _____

Facsimile: _____

Email: _____

If to Gilead:

Gilead Sciences, Inc.

333 Lakeside Drive

Foster City, California 94404

Attention: Corporate Legal Affairs

Tel (for courier use): +1.650.574.3000

Facsimile: +1.650.522.5771

Email: legal_clinical@gilead.com

9.10 Force Majeure. If either Party's performance of this Agreement is prevented, restricted or delayed (either totally or in part) for reasons beyond the affected Party's reasonable control and is not due to the action or inaction of such Party, the affected Party will, upon giving notice to the other Party, be excused from such performance to the extent of such prevention, restriction or delay; provided, that, the affected Party will use commercially reasonable efforts to avoid or remove such causes of non-performance and will continue its performance whenever such causes are removed.

9.11 Governing Law. This Agreement shall be governed by the laws of the state of Illinois, without regard to any choice-of-law principles.

FOIA. Gilead acknowledges and agrees that Institution, as part of a public body is required to by law to comply with the Illinois Freedom of Information Act ("FOIA") (5 ILCS 140/1 et seq.). Gilead must designate, in writing to Institution, any information Gilead deems Gilead Confidential Information and asserts to be exempt from disclosure under § 7(1) (i.e. 5 ILCS 140/7(1)(b)), § 7(1)(g) (5 ILCS 140/7(1)(g)) or other applicable FOIA exemption. If any Gilead Confidential Information that Gilead has asserted is exempt from disclosure is subject to FOIA request, Institution will respond to the FOIA request with the Gilead-asserted FOIA exemption and withhold disclosure of the Gilead Confidential Information. Institution will notify Gilead of the FOIA request and may require Gilead to submit further written justification of the Gilead-asserted FOIA exemption. Failure of Gilead to designate as exempt from disclosure under an applicable FOIA exemption shall not be conclusive that the information is not confidential and exempt from disclosure under FOIA. However, if Gilead has not asserted exemption from disclosure for any Gilead Confidential Information subject to FOIA request, Institution may determine whether Institution will or will not withhold the Gilead Confidential Information in response to the FOIA request. Institution will use best efforts to notify Gilead of the FOIA request and give Gilead three (3) business days from the notice date to assert an applicable FOIA exemption from disclosure. Additionally, Institution will not oppose any action of Gilead to obtain a declaratory judgment, protective order or other appropriate remedy in response to a FOIA request of Gilead Confidential Information. To the extent Institution is assessed attorneys' fees or court costs as a result of assisting Gilead in asserting a FOIA exemption from disclosure of certain Gilead Confidential Information, Gilead will indemnify and

hold harmless Institution from and against such expenses.

9.13 Cooperation with Inspector General. Gilead, by entering into this Agreement, is subject to and required to abide by all applicable provisions of the Office of the Independent Inspector General Ordinance set forth in Cook County Code of Ordinances Section 2-281 et seq. Gilead’s subcontractors, licensees, grantees or persons, which have a contract, license, grant or certification of eligibility for contracts with Cook County, including Institution, must abide by all applicable provisions of the Office of the Independent Inspector General Ordinance.

IN WITNESS WHEREOF, the Parties have entered into this Agreement as of the Effective Date by their duly authorized representatives. Under a Special Power of Attorney, Gilead has appointed and authorized Syneos Health, LLC to execute this Agreement in the name and on behalf of Gilead, thus binding Gilead to the duties and obligations set out in this Agreement.

Cook County, through its Cook County Health & Hospitals System d/b/a Cook County Health
By: _____
Name _____
Title: _____
Date: _____

SYNEOS HEALTH LLC on behalf of GILEAD SCIENCES, INC.
By: _____
Name _____
Title: _____
Date: _____

Acknowledgement by Investigator

I have read this Agreement and the Protocol for the Study, and I understand my obligations and those obligations of Institution. I will carry out my obligations and will assist in carrying out the obligations of Institution in compliance with this Agreement, the Protocol and all applicable laws, rules, guidance, and regulations including regulations of the FDA governing the conduct of clinical studies. I represent that I am a licensed medical practitioner in good standing under state and national law, and I am duly authorized to conduct this Study at Institution’s facilities. I consent to public disclosure of information about me by Gilead as required by applicable law, including, but not limited to my name as Investigator of the Trial at Institution, and the amount of the funding provided under this Agreement

MONICA MERCON, MD:

(Signature)

(Print Name and Title)

(Date)

EXHIBIT A

BUDGET AND PAYMENT SCHEDULE

GS-US-528-7614

1. **Payee.** Institution's payee under the Agreement shall be Ruth M Rothstein Core Center _____, which must be the same name as on the Institution's W-9 or W-8 form (referenced in Section 2 below), , and the Payee Information in Section 11 below.
2. **Payments.** All payments shall be by Electronic Bank Transfer (bank or wire transfer fees shall be the responsibility of the Institution) and conditioned upon a) performance of the Agreement in accordance with its terms, b) delivery to Gilead of a completed and signed W-9 or, for non-US payees, a completed and signed W-8,. Failure to complete the required tax forms may result in non-payment, or delayed payments.
3. **Terms of Certain Payments.** The following fees will be paid upon satisfaction of additional terms and conditions as follows:
 - a. **Start-Up Payment:** All Start-up fees designated in the attached budget as payable "Upon CTA Execution," shall be Auto-Paid within forty-five (45) days of when the Agreement is fully executed and delivered to Gilead. An invoice will not be required for the Start-up fees that are payable "Upon CTA Execution" to be paid.
 - b. **Interim Subject Payments:** Each visit fee, as outlined in the attached budget, shall be Auto-Paid subject to the following conditions: completion of a trial visit by an Enrolled Subject (as defined below) in accordance with the Protocol; and Gilead's acceptance of the corresponding Case Report Form (CRF) for the visit. An "Enrolled Subject" as used herein is defined as a subject who meets the Protocol eligibility criteria and has signed the Informed Consent Form (ICF) and HIPAA Authorization (or country-specific equivalent), as approved by Gilead. The Payee shall issue an invoice corresponding to each quarterly proposal.
 - c. A screen failure occurs when a candidate for the Trial fails to meet the eligibility criteria set out in the Protocol, and is, therefore, not enrolled in the Trial. Institution will be Auto-Paid at the screen failure rate (in the budget) for the procedures used during screening to determine the subject may not be enrolled, in the same manner as for Visit Fees

referenced above. The screen failure payment rate and the maximum # of screen failure(s) are listed in the attached budget. The maximum number of screen failures may be increased by Gilead's prior written approval, in which case no amendment to the Agreement shall be required, and investigative site will invoice for any approved additional screen failures.

4. **Invoice Required.** All payments under the Agreement (other than those to be Auto-paid) as described in Section 3 above (i.e. "Autho-Paid"), shall be issued within forty-five (45) days following receipt of the invoice accompanied by substantiating documentation and receipts, and as otherwise described below.
5. **Subject Stipend or Travel Reimbursement.** If not included within a scheduled Trial Visit, Gilead will pay applicable expenses for Subjects related to the Trial which are listed in the attached budget, or in the IRB approved ICF used in the Trial, upon receipt of an invoice. In the event of a conflict between the stipend or travel reimbursement amount reflected in the Trial Visit and the Informed Consent Form ("ICF"), the amount reflected in the ICF controls.
6. **Target Enrollment Number.** Enrollment for this Trial is competitive and the Target Enrollment Number (referenced in the attached budget) is intended for budgetary purposes only. If required by Institution, the Target Enrollment Number may be increased upon Gilead's prior written authorization, in which case no amendment to the Agreement shall be required. In order to manage the total trial enrollment, Gilead, at its sole discretion, may suspend screening and/or enrollment at any site or trial-wide at any time.
7. **Additional Expense Reimbursements.** Gilead shall pay Trial-related expenses not set forth in the attached budget if pre-approved by Gilead in writing, in which case no amendment shall be required.
8. **Invoicing Instructions.**
 - Invoices shall be submitted within 45 days upon completion of services.
 - Request For Invoice (RFI) will NOT be issued for subject visits and/or invoiceables.
 - A single invoice per PDF file (other formats than PDF are not accepted, such as Word, JPG, Excel, etc).
 - Supporting documentation must be included in the same PDF as invoice.

Syneos Health LLC shall act as the payment agent ("Payment Agent") for services performed in this Agreement. All invoices must be issued to the following as instructed in English:

Gilead Sciences, Inc.
C/o: Syneos Health LLC
Attn. Investigator Payment Department
1030 Sync Street
Morrisville, North Carolina, 27560, USA
Re: 7076600
E-mail: SM_InvestigatorPayments@Syneoshealth.com

All invoices and payment related queries - including the Project Code referred to above - must be sent to: E-mail: SM_InvestigatorPayments@Syneoshealth.com

Payment Currency:	
Indicate Payment Method (Check or Electronic):	
Remittance Email:	
Remittance Information for Check Payments.	
Remittance Address:	
Remittance Information for Electronic Payments.	
Bank Name:	
Bank Country:	
Name on Bank Account:	
Routing Number/SWIFT:	
Bank Account Number:	
IBAN (if applicable):	
Additional Banking Information (if applicable):	

Please Note: Changes to the banking information will not require an amendment. If there is a change in the banking information, please inform us at **SM_InvestigatorPayments@Syneoshealth.com**.

Please insert budget tables as appropriate (paste special - picture enhanced metafile landscape).