BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC

KELLEY-ROSS PHARMACY GROUP
SUBJECT INFORMATION AND INFORMED CONSENT FORM

Protocol Title: **I**mplementation and **D**elivery of **L**enecapavir for PrEP **in** a **C**ommunity Pharmacy Setting (L4P in Pharm)
Protocol #: IN-US-974-7746
Sponsor: Gilead Sciences
Principal Investigator: Elyse Tung, PharmD, BCACP
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KEY INFORMATION ABOUT THIS RESEARCH STUDY

You are being asked to be a subject in a research study because are at least 18 years of age and are seeking pre-exposure prophylaxis (PrEP) for HIV prevention.

The following table is a concise and focused presentation of key information to assist you in understanding why you might or might not want to participate in the research.

Purpose	The purpose of this research is to assess if a pharmacist-managed clinic program delivering an injectable form of PrEP is feasible.
Experimental/ Investigational	You will not receive any experimental drugs or procedures as part of this study.
Voluntary Participation	Your decision to be in this study is voluntary.
Withdrawal	If you decide to be in this study and then change your mind, you can leave the study at any time without penalty.
Length of Participation	The length of time you are in this study and number of study visits depends on how long you decide to be on PrEP. It may last up to 12 months.
Procedures	The main procedures in the study include: • Baseline participant survey • Follow-up participant surveys • Discontinuation survey The study healthcare provider will explain which procedures are being done for research, and which would be done as part of your standard care even if you do not participate.
Risks	There are not expected to be any physical risks to you as part of this study.
Benefit	There is no direct benefit to you from taking part in this study. However, the study results may help people in the future.
Alternatives to Study Participation	Your alternative is to not take part in the study.
Costs	You and/or your insurance company will be responsible for the costs of all items and services during the research study.
Confidentiality	There are provisions in place by the study protocol and study site to help protect the privacy and confidentiality of your personal health information and study information.

This overview does not include all of the information you need to know before deciding whether or not to take part. Much additional detail is given in the full consent document, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.

INFORMED CONSENT FORM

This consent form explains the research study. Before you decide to be a part of this study, you need to know why the research is being done, what it will involve and the risks and benefits. Ask the study doctor and study staff to explain anything in this form or if you want more information. Please take time to read this form carefully. Feel free to discuss it with your relatives, friends, and your primary care physician. If you agree to take part in this research study, you must sign this consent form.

DISCLOSURE OF FINANCIAL INTERESTS

Gilead Sciences, the sponsor of this study, is providing funds to Kelley-Ross Pharmacy Group for conducting this research study.

BRANY maintains a financial interest disclosure process by which people who conduct research must disclose any financial investments (for example stock shares or patent holdings), or payments (for example, for consulting or speaking engagements) that are related to the research.

For the study you are considering joining, Elyse Tung, PharmD, the Principal Investigator, and Peter Shalit, MD, the Medical Director, disclosed information about compensation received in the last year for advisory board and speaker bureau work for the study sponsor, Gilead Sciences, Inc. Elyse Tung,PharmD, and Peter Shalit, MDalso expects to receive compensation from the study sponsor in the next 12 months.

If you would like more information about this matter, please ask the researchers and they will assist you.

PURPOSE OF THE STUDY

The purpose of this study is to evaluate to assess if a pharmacist-managed clinic program delivering an injectable form of PrEP is feasible.

NUMBER OF SUBJECTS AND LENGTH OF STUDY PARTICIPATION

About 75 subjects are expected to participate in this study at 1 research site in the United States.

Your participation in this study is expected to last 12 months.

STUDY PROCEDURES

This study will add procedures for the next 12 months to the procedures you will already have as part of your regular PrEP care. Your regular PrEP visits will include blood draws for laboratory tests, a check in on how you are doing with the medication, and an injection. If you choose to take part in this study, you will have additional procedures associated with your first injection visit and every follow-up visit, as described below.

Release of Information: We will ask that you complete a release of information form today.

Surveys: We will ask you to complete an online survey at your first injection appointment, 4 to 6 weeks after your first injection appointment, at every follow-up appointment, and at the end of the study. The surveys will ask you questions about you (for example your age, race, and gender), your sexual practices, and your experiences with PrEP. You may refuse to answer almost any question in the survey that you do not wish to answer. We will require that you

answer questions about the study interventions, including how acceptable you find the intervention. We require answers to these questions because this information is needed to meet the study aims.

You will be asked to verbally consent to HIV testing and may be counseled. HIV related information may be shared with other members of the research team besides the principal investigator

If you do not respond to the survey within 2 weeks, we will ask you not to continue in the study.

Time: We expect that the research procedures for today's visit, including consenting for the study, will take approximately 60 minutes. The online survey at your first injection visit will take approximately 10 minutes. The online survey at your follow up visits will take approximately 10 minutes.

SUBJECT RESPONSIBILITIES
As a subject in this study, you will have certain responsibilities, including the following:

- Attend all study visits and, if needed, reschedule appointments as soon as possible
- Follow the instructions of the study team
- Take the study drug as directed
- Tell the study doctor all medications that you are taking and check with the study doctor before taking any new medicines (including prescription, over-the-counter, vitamins and herbal supplements)
- Tell the study staff any time you do not feel well or if you have any side effects

RISKS AND DISCOMFORTS
There are no physical risks expected from participating in this study. There is the risk of loss of confidentiality of your medical and personal information collected for this study.

Surveys: The questions we ask on the surveys about your sexual behavior and experience with PrEP may make you feel uncomfortable. In addition, it is possible that someone else may see your replies to the survey if you take the survey in a place where other people are present. To protect your confidentiality, we recommend you take the surveys in a private location, where nobody can see your replies. We will ask you not to enter any identifying information into the study surveys.

Information about possible side effects of your PrEP medication can be found in the patient information leaflet from the package insert included with your medication. Please let the study team know if you think you may be experiencing side effects at any time during the study.

Please let the study team know if you become pregnant or think you may be pregnant at any time during the study.

NEW INFORMATION
You will be notified in a timely way if important new findings become known that may affect your willingness to continue in the study.

<u>Clinically Relevant Research Results</u>
The study doctor will explain if and when you will receive individual research results that may have clinical significance.

BENEFITS
We cannot promise any benefit to you or others from your participation in this research.

ALTERNATIVES TO STUDY PARTICIPATION
You do not have to participate in this study to receive PrEP care. The study doctor will discuss study alternatives with you and their risks and benefits.

COSTS OF PARTICIPATION
You and/or your insurance company will be responsible for the costs of all items and services that are considered standard of care for HIV prevention. You would have received these services if you were not enrolled in this research study and/or that your physician believes are medically necessary to treat you. You should discuss possible costs of study participation with the study staff and/or your insurance company.

REIMBURSEMENT
You will receive a $50 gift card for each of the surveys you complete in this study.
If you leave the study early, you will be reimbursed only for surveys you complete.

Tax law may require the payer (e.g., research institution or third party) to report the amount of payment you receive from that payer to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this reporting would take place if you received $600 or more from the payer in a calendar year. You would be responsible for paying the taxes on the payment you received from the study.

You will not receive payment of any kind for your information and specimens (even if identifiers are removed) or for any tests, treatments, products or other things of value that may result from this research study.

COMPENSATION FOR INJURY
For medical emergencies, call 911. If you become ill or are hurt while you are in this study, contact your study doctor immediately. The study doctor will assist you in obtaining appropriate medical treatment. The institution will not be responsible for the costs of treatment caused by the properly performed study procedures.

The sponsor will pay for reasonable and necessary medical treatment of injuries and illness that are a direct result of study procedures by the study protocol and that were done correctly and only because you were in this study.

The sponsor will not cover the costs of your study-related injury or illness if:

- The sponsor and/or the study doctor do not think the condition or injury is a direct result of your being in the study;
- The injury is attributable to the underlying disease or a pre-existing medical condition or the natural progression of an underlying disease;
- The injury was the result of a failure to follow the study protocol or instructions or misconduct by the study staff.

No other compensation will be offered by the sponsor or Kelley-Ross Pharmacy Group or Biomedical Research Alliance of New York, including for things such as lost wages or discomfort. You are not waiving any legal right to seek additional compensation through the courts by signing this form.

CONFIDENTIALITY

To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study will be submitted to the study sponsor and to the U.S. Food and Drug Administration. It may be submitted to governmental agencies in other countries. Medical records, which identify you and the consent form signed by you, will be looked at by the sponsor or the sponsor's representatives and may be looked at by the FDA and other regulatory agencies, the Institutional Review Board, and the Biomedical Research Alliance of New York. While these parties are aware of the need to keep your information confidential, total confidentiality cannot be guaranteed. The results of this research project may be presented at meetings or in publications; however, you will not be identified in these presentations and/ or publications.

If you take part in this study, you will be assigned a unique subject code to help protect your privacy. Your study records and study samples will be labeled with this code that does not directly identify you. The study site staff securely stores the linking code between your name and study information.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you. If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health, including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about laboratory test results
- Results from diagnostic and medical procedures including but not limited to X-rays, physical examinations and medical history
- Billing records

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study. Your information may be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor or are owned by the sponsor. Information about you and your health which might identify you may be given to:

- The U.S. Food and Drug Administration
- Department of Health and Human Services agencies
- Governmental agencies in other countries
- Biomedical Research Alliance of New York (BRANY)
- The Institutional Review Board
- Accrediting agencies
- Data safety monitoring boards

- Health insurers and payers
- Other individuals and organizations that analyze or use your information in connection with these research activities, including laboratories, contract research organization and study sites (if you transfer to another study site)

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the U.S. federal privacy laws. However, these groups are committed to keeping your personal health information confidential. If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose. The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

This authorization does not have an expiration date. If you do not withdraw this authorization in writing, it will remain in effect indefinitely.

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. You do not have to sign this consent form. If you choose not to sign this consent form, you will not be able to be in this research study. Your decision not to sign this consent form will not have any effect on your medical care and you will not lose any benefits or legal rights to which you are entitled. You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you may not be allowed to look at or copy your information until after the research is completed.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor at the address on the front of this informed consent form. If you withdraw your permission, you will not be able to continue being in this study, but you will not have any penalty or loss of access to treatment or other benefits to which you are entitled. When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Notice Concerning HIV-Related Information: HIV-related information that either is collected as part of the research or that may already exist in your medical record might be accessed for the research by the research staff and the study sponsor but will not be shared with others without your authorization, unless federal or state law requires the disclosure. You have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the agencies that are responsible for protecting your rights.

Collection of Identifiable Private Information or Identifiable Biospecimens:

- Your information and biospecimens collected as part of this research study, even if identifiers are removed, will not be used, or distributed for future research studies.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may stop your participation at any time, without penalty or loss of benefits or medical care to which you are otherwise entitled. If you decide to leave the study, please tell the study doctor.

Your participation in this study may be stopped without your consent at any time and for any reason by the study doctor, the sponsor, the FDA and other regulatory authorities. Reasons you may be withdrawn from the study include it is determined to be in your best interest, you need treatment not allowed in this study, you do not follow the study instructions, the study is stopped, or for other administrative reasons. If you leave the study early, you may be asked to return to the study doctor's office for a final study visit for your safety.

CONTACTS FOR QUESTIONS, COMPLAINTS, CONCERNS

If you have any questions or requests for information relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, or if you have a study related injury, you may contact Dr. Elyse Tung at 206-641-7766.

If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research. The IRB is a committee that reviews research studies to help protect the rights and welfare of study subjects.

STATEMENT OF CONSENT - SIGNATURES

By signing this form, I confirm the following:

- I have read all of this consent form.
- All of my questions have been answered to my satisfaction.
- I can leave the study at any time without giving a reason and without penalty.
- I agree to the collection, use, sharing and analysis of my personal health information and study information collected as part of this study by the sponsor and other authorized persons and regulatory agencies as described in this form.
- I will be given a copy of this signed and dated consent form to keep.
- I do not give up any legal rights that I would otherwise have if I were not in this study.

I voluntarily agree to participate in this study.

Subject: Name (Print)	Signature	Date
Person Obtaining Consent: Name (Print)	Signature	Date