

PrEP HAIR TEST STUDY STUDY INFORMATION SHEET

We would like to ask you to participate in this study if you are taking oral PrEP (Truvada®) for HIV prevention. You may be eligible for the study if you meet all the following criteria:

- Age 18 to 49 years;
- Male **OR** transgender woman;
- Have taken oral PrEP for at least 1 month (daily oral regimen);
- Had 5 or more drinks of alcohol on an occasion or had 15 or more drinks per week in the last 30 days **OR** used any of the following substances for 2 or more times in the last 30 days: stimulants (ex: cocaine, methamphetamine, ecstasy – MDMA), cannabis (marijuana), or opioids (ex: norco, heroin, fentanyl, oxycontin); and,
- Able to provide a small hair sample (100-200 strands) cut near the scalp from the back of your head for a hair analysis.

Your participation in this study is completely voluntary. Your decision about participation will not affect your medical care or your healthcare benefits at Kaiser Permanente. The results of the hair analysis will not be recorded in your medical record.

If you are eligible and agree to participate in this study, a trained study staff member from the Department of Research & Evaluation will schedule a one-time visit at a Kaiser Permanente facility for the hair sample collection.

Why is this study being done?

Long-term alcohol use and substance use may affect PrEP use and the effectiveness of PrEP for HIV prevention. The Department of Research & Evaluation of Kaiser Permanente Southern California is planning a study to assess the relationship over time between heavy alcohol and substance use with taking PrEP as prescribed. In preparation for a future larger-scale study, we propose to conduct this pilot study to evaluate the feasibility of measuring biomarkers of PrEP use and exposure to alcohol and other commonly used substances in small hair samples. The results of the pilot study will help the investigators to collect preliminary data and better design the future study.

This study protocol has been reviewed and approved by the Kaiser Permanente Southern California Institutional Review Board. The study principal investigator is Rulin Hechter, MD, PhD in the Department of Research & Evaluation at Kaiser Permanente Southern California.

How many people will take part in this study?

The study plans to recruit about 20 eligible adults. Recruitment will close once we reach the targeted number.

What will happen if I take part in this research study?

If you participate in this study, you will be scheduled for a one-time in-person visit for hair sample collection. The hair collection will be done by a trained study staff member in a private room at a Kaiser Permanente facility in Los Angeles or Pasadena. Please avoid having your hair cut too short before your scheduled visit. If your hair is too short for collection (less than 1 centimeter or half inch long) at the time of your visit, you may be asked to reschedule after 2-4 weeks.

You will receive the detailed location and time for your visit through email or text message (whichever you prefer) before your visit. The email will come from our secure study email address:

GoPrEP@kp.org. You will receive reminder phone calls or text messages from study staff about a week before and the day before to confirm your scheduled visit.

During your scheduled visit, a trained study staff member will meet you in a private room and explain the procedure of hair collection, answer your questions, and obtain your oral consent before collecting the hair sample. The study staff member will follow safety protocol for COVID-19 prevention during the visit and wear a surgical or KN95-level mask and procedure gloves during the visit.

About 100-200 strands of hair (about the size of a pen) will be clipped using a pair of sanitized scissors from as close to the scalp (proximal end) as possible. Ideally, hair should be collected from the underneath layer of the occipital (back) region of the scalp. Hair can be cut from other regions of the scalp or from more than one place if you would prefer. In general, people lose about 100 strands from their head every day, and 50 strands of cut hair is not cosmetically noticeable.

After a hair sample is successfully collected, you will receive a \$50 gift card as a thank you.

Your hair sample will be sent to a certified research lab at University of California, San Francisco (UCSF) for hair analysis. The results of the hair analysis will be provided to the study team. Because this is a research pilot study, you will not receive the test results.

How long will I be in the study?

A one-time in-person visit will be scheduled for the hair sample collection. The hair sample collection procedure is non-invasive and takes about 5-10 minutes. The entire visit may take about 20-30 minutes for study staff to answer your questions, obtain verbal consent, and complete the hair collection procedure.

Can I stop being in the study?

If at any time you decide this study is not for you, you may let study staff know and/or call the study's toll-free phone number (833-242-8497) to leave a message for the study team.

What risks can I expect from being in the study?

Some people may feel nervous about providing a hair sample. A total of 100-200 strands hair (about as big around as a pen) will be cut close to the scalp in an area at the back of your head. Trained study staff will cut the hair so that it is not cosmetically visible. The average person loses about 100 strands of hair a day naturally.

You may be at risk of loss of confidential information when you communicate with study staff via email, if your email can be accessed by another person or your email account is compromised. The study team will use highly secure email servers to minimize the risk of loss of confidential information and limit the confidential information disclosed in the communication as needed. You may also reduce the risk by using an email address secured by a password that is only known to yourself.

If you would like to discuss about possible risks, please reach out to study staff via GoPrEP@kp.org or by calling the study's toll-free number (833-242-8497) to leave a detailed message for us to call you back.

Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. However, your contribution to this pilot study will help the investigator team to evaluate the feasibility of the future study. The future larger-scale study will generate important data to assess how long-term alcohol and substance use

may influence PrEP use and risk of HIV infection and inform tailored PrEP implementation programs to benefit persons who may be at higher risk of HIV infection.

What other choices do I have if I do not take part in this study?

Your decision about whether you participate is entirely voluntary. You do not need to do anything else if you choose not to take part in this study. Your decision will not affect your medical care or your healthcare benefits at Kaiser Permanente.

Will information about me be kept private?

Your name and any identifying information you provide will be kept private in password protected electronic files. Any paper record that may contain your information will be kept secure. Your participation and your hair test results will not be entered into your medical record. You will provide verbal consent before a hair sample is collected. We collect your contact information only so that we may schedule your visit and to provide your \$50 gift card as a thank you. No names or identifying information will be included on study materials related to this research project. The results will not be linked to identify you at a later time.

Your Kaiser Permanente doctor may have referred you to our study staff, but s/he will not have access to any of the study records or results. We will keep the hair sample and any personal information in a locked file cabinet and separate password protected electronic file until sent to the lab. All personal records with your information will be destroyed after the study is completed according to the policy of Kaiser Institutional Review Board. Information you share during your participation will not be recorded in your Kaiser Permanente medical record.

What are the costs of taking part in this study?

There are no monetary costs for participating in this interview.

Will I be paid for taking part in this study?

After you provide a hair sample, we will offer you \$50 in the form of an Amazon.com or Target.com e-gift card (at your preference) as a thank you for your participation.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study now, you may still choose to leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. Your decision will not affect your medical care and your healthcare benefits at Kaiser Permanente. If you have any questions about your rights as a research participant, you may contact Armida Ayala, PhD, Director, Human Research Subjects Protection Office at 626-405-3665 or armida.ayala@kp.org

Who can answer my questions about the study?

You can talk to one of the research staff about your questions, concerns, or complaints about this study. You may call the study toll-free number 833-242-8497 to leave a detailed message for the study team to call you back or email GoPrEP@kp.org.

If you wish, we will send you a printed copy of this information sheet.