

Request for participation in the PrEP evaluation study

PrEP group

Background and study objective.

Norway is the first country in Europe to provide PrEP (HIV prevention treatment) free of charge to its users. This is a new service and we need your help to look at PrEP in individual users, as a HIV prevention tool and its effect on society itself. In particular we want to learn more about the impact of PrEP on people's general and sexual health, practice, as well as their everyday experience of treatment and general follow-up.

What does the evaluation study entail?

As a participant in this PrEP evaluation study, you will follow the same examination and follow up schedule as all of our PrEP users. We will however ask you more detailed/ systematic questions about your lifestyle, sexual behaviour and quality of life. We will ask you to register information yourself, before your follow-up visits. This can be done electronically; alternatively you can fill out a paper form. We will also ask you to keep a "medication diary". Blood samples will be collected at normal follow-up appointments.

If you started using PrEP, prior to official enrolment in the study, we would like to use relevant retrospective data (past information) back to the time when you started PrEP. By consenting to participate in the study, you also agree that we can register available relevant data from the time you started PrEP.

Additional investigations will be requested according to your individual health needs. All samples are sent for analysis at the Department of Microbiology and Department of Clinical Chemistry, Ullevål, Oslo University Hospital in accordance with standard procedures. You will be asked specifically if further samples are required for research purposes.

Potential benefits and drawbacks

Participation in the study offers no particular personal benefit, other than you will get a better overview of your sexual and psychosocial health. This may identify that you would benefit from additional measures or support, which may otherwise have gone undetected. We hope your participation in the study will improve your personal knowledge of PrEP. It also gives you the opportunity to provide basic, important information which may inform providers and assist in future planning of resources for PrEP services in general.

What happens to your samples and information about you?

Your results and information will be processed without your name, personal identification number or other directly identifiable information. It will be registered in a secure data register approved by the Regional Committee of Ethics. This is not a clinical electronic patient record, but a separate research database. A code will link you to your information/test results and will exist as a separate list which is stored securely. Only authorised personnel affiliated with this study have access to this list, and only they can identify you. When published it will not be possible to identify you from the results of the study. If you agree to participate in the study, you will be entitled to access to the information registered about you. You are entitled to have any incorrect information we have registered corrected. If you withdraw from the study, you can request collected information to be deleted. All information on the secure data register will be deleted no later than ten years after the initial registration, as a matter of routine. Your test results and information will only be used as outlined in the study objective.

Voluntary participation

Study participation is voluntary. If you do not wish to participate, you do not need to give a reason for your decision, it will have no consequences for your future treatment at the hospital.

If you wish to participate, please sign the declaration of consent overleaf. You may withdraw your consent later without it affecting your future treatment at the hospital. If you wish to withdraw at a later time, contact principal investigator **Anne Olaug Olsen, tel. (+47) 23 07 58 40.**

Consent to participation in the study

I am willing to participate in the study.

1)

2)

3)

Name of the project participant in BLOCK LETTERS

Signature of the project participant

Date

Confirmation that information has been provided to the study participant

I hereby confirm that I have provided information about the study.

1)

2)

3)

Name in BLOCK LETTERS / Role in the study

Signature

Date