# EXPrESSIVE

Together we can help advance

# HIV prevention research

## Learn about the EXPrESSIVE clinical research study

## for people who could be exposed to HIV

## What is a clinical study?

Clinical studies are research studies that help doctors find out if study medicines (alone or with other treatments) are safe and if they can help prevent, find, or treat diseases or conditions. Clinical studies are carefully controlled research studies that are done to get a closer look at investigational treatments and procedures.

## What requirements are in place to help protect clinical study participants?

Regulations and policies are in place to help ensure studies are conducted according to strict scientific and ethical principles. Before a clinical research study can begin, an Institutional Review Board (IRB) or Research Ethics Committee (REC) must review and approve the study. The primary purpose of these committees is to protect the rights, safety, and well-being of research participants while ensuring ethical standards are met.

## What is the goal of the EXPrESSIVE clinical research study?

Researchers are testing an investigational study medicine, which is a type of PrEP (pre-exposure prophylaxis).

PrEP is a medicine that may help lower the chance of becoming infected with human immunodeficiency virus (HIV) in people at risk of being exposed to the virus.

Study participants will take either the investigational study medicine or an approved PrEP medicine (comparator) to assess:

- The safety of the investigational study medicine
- How the investigational study medicine may work in the body
- Any side effects from the investigational study medicine (tolerability)
- How well the investigational study medicine may help reduce the chance of getting HIV-1 infection compared to an approved PrEP medicine

The investigational medicine is experimental. It is not an approved PrEP medication.

## Do I qualify?

You may qualify to participate in the EXPrESSIVE study if you are at least 16 years of age and:

- Do not have HIV
- Are a cisgender man (assigned male at birth and identify as male), transgender woman (assigned male at birth and identify as female), transgender man (assigned female at birth and identify as male), or gender nonbinary (assigned any gender at birth and do not identify as exclusively male or female)
- Have had receptive anal sex without a condom in the past year (not counting sex in a committed relationship) and **have at least 1** of these situations:
  - Had receptive anal sex with 2 or more partners in the last 3 months, no matter if you used a condom or not.
  - Had rectal or urethral infections like gonorrhea, chlamydia, or syphilis in the last 6 months.
  - Used any stimulant drugs while having sex in the last 3 months.

There are additional eligibility criteria, which the study team can discuss with you. There may be risks related to participating in this clinical research study.

## What will happen in this study?

### Before you enroll in the study

Before joining this study, you will have a screening visit to find out if you are eligible to join. If you can and want to join the study, you will read and sign

an informed consent form (ICF). If you are under 18, your parents/guardian will sign the ICF, and you will sign an assent form. The ICF gives you details about the study, including the medical tests you can expect and the possible risks and benefits of participating. By signing this form, you agree that the study details have been explained to you, your questions have been answered, and you agree to participate. The informed consent form is not a contract, and you are free to leave the study for any reason at any time.

### During the study

You will be randomly assigned to 1 of 2 groups, similar to flipping a coin, giving you a 50/50 chance of receiving 1 of the following:

- The investigational study medicine (taken monthly) + daily placebo tablets
- The approved comparator PrEP medicine (taken daily) + monthly placebo tablets

## During the study (*Cont.*)

You, your study doctor, and the study staff will not know what study medicine you are getting. In case of a health emergency, they can find out.

The placebo tablets look like the investigational study medicine or comparator medicine but have no active ingredients. Using placebos helps researchers better understand the effects of the investigational study medicine.

You will take the investigational study medicine or comparator PrEP medicine for up to 30 months (around 2.5 years), and you will have monthly study clinic visits. During these visits, the following medical tests and exams may be conducted, including physical exams, urine (pee) tests, throat and rectal swabs, blood draws, pregnancy tests (if you are able to get pregnant), and completion of surveys. How long you are in the study depends on when you start the study.

## Follow-up

After you stop taking your assigned study medicine, you will enter the 42-day follow-up period. You will visit the study site up to 2 times and have 1 phone call visit. For the first 28 days of follow-up, all participants will take the daily comparator PrEP medicine.

## What if I want to leave the study?

You can decide to stop taking the study medicine or leave the study before the study is over. If you do, the study staff will ask you to return to the study site as soon as possible after your last dose for medical tests. You will also be asked to still go to your remaining scheduled study visits.

## Do I have to pay to be in this study?

All study medicines and study-related tests will be provided at no cost.

**For more information, including possible risks and benefits of participation, please contact:**

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