

# PARTICIPANT INFORMATION SHEET

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| Study title:       | <b>The NZ PrEP Study: A demonstration Project of HIV pre-exposure prophylaxis in Aotearoa, New Zealand</b> |                       |                    |
| Locality:          | <b>Auckland Regional Sexual Health Service</b>   | Ethics committee ref: | <b>16/NTA/112</b>  |
| Lead investigator: | <b>Sunita Azariah</b>  | Contact phone number: | <b>0800 739432</b> |

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Kia mahara ki ngā kupu maioha ki tenei whakatakanga, Nō reira, tēnā koe.

Warm greetings to you and welcome to this project. You are invited to take part in a study on PrEP (or HIV pre-exposure prophylaxis). Taking part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do choose to take part but change your mind later, you can pull out of the study at any time. This study has been funded by **Gilead Sciences** and will take place over 24 months from the start of enrolment.

This information sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what taking part would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today. You may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the consent form on the last page of this document. You will be given a copy of this information sheet and the consent form to keep.

This document is 6 pages long with a separate 2 page consent form. Please make sure you have read and understood all the pages.

## What is PrEP?

“PrEP” stands for “**pre-exposure prophylaxis**”. The word “prophylaxis” –means “to prevent”-in this situation it means to prevent HIV infection.

PrEP, is a combination of 2 HIV medicines called tenofovir and emtricitabine called **Truvada** (brand name) which is manufactured by Gilead Sciences. Truvada is currently licensed in New Zealand to treat people living with HIV.

Truvada when taken as PrEP can also **prevent** HIV infection by blocking important pathways that the HIV virus uses to set up an infection. Truvada is not licensed or funded in New Zealand for PrEP but it is licensed for PrEP in Australia and the United States.

## What is the purpose of the Study?

The purpose of this study is to find out if the use of PrEP can lower the number of new HIV infections in Takatāpui, gay or bisexual men in New Zealand.

Studies overseas have found that the use of PrEP is very good at preventing most HIV infections in men who are at higher risk of getting HIV if taken correctly.

As the use of PrEP has not been trialled before in New Zealand, Auckland Regional Sexual Health Service (ARSHS) is working with other organisations in the HIV sector to find out if PrEP can be used successfully here and what are the possible benefits and harms.

Information from this study will help guide future decisions by the Ministry of Health and PHARMAC as to whether PrEP should be funded in New Zealand in the future.

PrEP is not intended to replace other effective HIV prevention methods such as condoms.

## What does taking part in this study involve?

You have been invited to take part because you may be at increased risk of getting HIV. However first a doctor or nurse will need to ask you questions about any health problems you may have and any other medicines (including recreational drugs) you may be taking that may mean it is unsafe for you to take PrEP.

If you seem suitable for PrEP, you will need to have a general health check, blood tests for HIV, and swab and urine tests for other STIs (sexually transmitted infections). Your blood will also be tested to see if your kidneys and liver are healthy. You will be asked questions about your sexual health including whether you use condoms and about recent sexual contacts.

**You can take part in the study only if these tests show that you do not have HIV and if PrEP medicines are likely to be safe for you to take.** You will need to sign a consent form that you have read and understood all the possible risks and benefits of taking PrEP and that you agree to have regular visits every 3 months for health checks.

**If your HIV test is positive we can provide treatment and support for this at the sexual health clinic.**

## Why do I have to have check-ups every 3 months?

As PrEP is a new form of HIV prevention not all the benefits and harms are yet known.

Your doctor or nurse will talk to you at every visit on how to reduce your risk of getting HIV and other STIs. They will also check that you have been taking your PrEP correctly. You will need blood tests for HIV and syphilis and to check your liver and kidneys are not being affected by the medication.

You will also need to have other tests such as swabs and urine tests to check for other STIs such as chlamydia and gonorrhoea. You will need to visit the clinic regularly as long as you stay on PrEP.

## On-line Survey

Another very important part of the study is to find out if people taking PrEP change their behaviour in any way as a result of taking PrEP. Taking part in the study means you agree to fill-in an on-line survey every 3 months. The survey will collect general information about your age, ethnicity and education. It will ask questions about your knowledge, beliefs and attitudes to PrEP, numbers of sexual contacts since your last clinic visit, use of condoms and recreational drugs. It will take about 20 minutes of your time to complete each time.

The study will go on for 24 months so you will need to be living in Auckland while you are taking part.

## Will I have to pay for my PrEP?

While you are taking part in the study your PrEP will be provided free of charge. PrEP is not yet funded in New Zealand so once the study finishes you will need to pay for the medication if you want to keep taking it. We can let you know what this may cost once the study finishes.

## Who should take PrEP?

PrEP is not for everyone. Doctors prescribe PrEP for some people who have a very high risk of getting HIV as they do not always use condoms for anal sex.

If you are Takatāpui or a gay or bisexual man you should consider PrEP if you sometimes or often have anal sex without using a condom, especially if you have a sex partner who you know has HIV and is not on treatment.

You may also be at higher risk of HIV if you have recently had an STI such as syphilis or if you often have sex while taking drugs or alcohol.

## What are the benefits of PrEP?

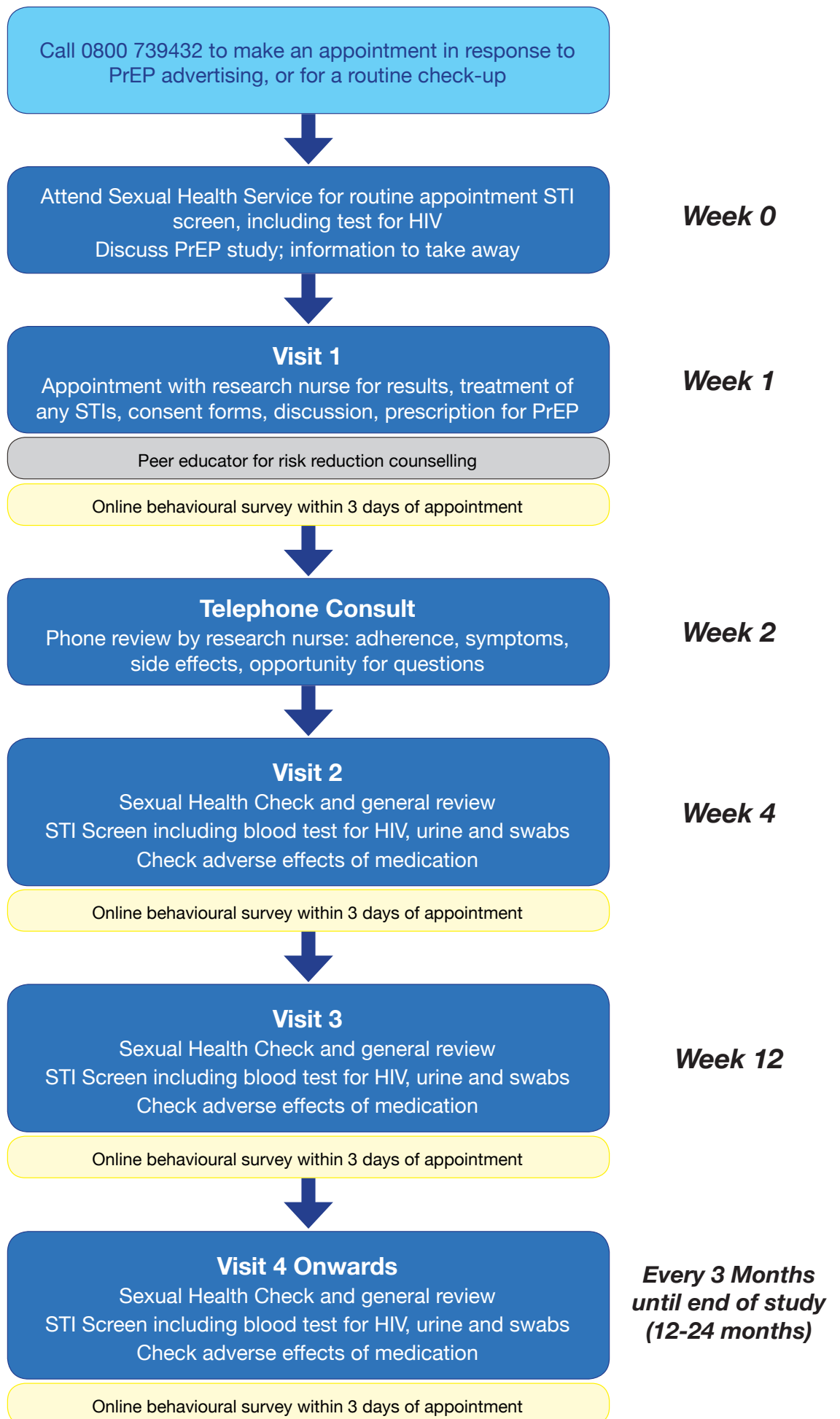
If PrEP is taken correctly studies have shown it blocks about 86% of new HIV infections.

However if you do not take PrEP pills every day, there may not be enough medicine in your bloodstream to block the virus.

You can think about PrEP in a similar way to condoms. When condoms are used correctly (which means nearly all the time) they provide very good protection against HIV as well as other STIs.

PrEP — like condoms—can't protect you if it's not used correctly! PrEP is not a vaccine and only provides protection from HIV so long as you continue to take it daily. Your doctor or nurse will talk to you about ways to help you take it daily so that it gives you the best protection against HIV infection.

# Participant Visit Schedule



## Does PrEP protect against all STIs?

No. PrEP only provides protection from HIV and does not prevent you getting other STIs like syphilis and gonorrhoea.

## Should I keep using condoms?

Yes -as just taking PrEP may not stop you getting HIV.

Condoms act as a physical barrier through which HIV cannot pass. When used correctly and no slippage or breakage occurs, condoms are over 90% effective at stopping the transmission of HIV because they prevent contact between body fluids containing HIV (semen, rectal fluids) and the parts of someone's body that can let in the virus (e.g rectum, penis).

### ***We recommend that you:***

- Always use condoms to reduce contact with semen, vaginal fluids, or blood.
- Do not share personal items that can have blood or body fluids on them, such as toothbrushes and razor blades.
- Do not share or reuse needles or other injection or drug equipment.

***You will get the most protection from HIV and other STIs if you take PrEP daily and always use condoms for anal sex.***

For more information on PrEP you can visit this website: <http://nzprep.org>

## Is PrEP safe?

PrEP is usually safe as long as you have been checked out by a doctor and you are taking it correctly.

Few serious side effects have been found so far in studies of PrEP. Some people had early side effects such as an upset stomach, diarrhoea or loss of appetite but these were mild and usually went away within the first month. Some people also had a mild headache. You should tell your doctor if these or other symptoms become severe or do not go away.

The medicines in PrEP may also affect the liver, kidneys and bones but these effects usually go away if the medicine is stopped. If you take part in the study you will need to have regular blood tests to check your liver and kidneys are OK.

Rarely some people can become allergic to the medicine and get a rash or more serious symptoms such as breathing problems or swelling of the face, lips or tongue. If you get any of these symptoms you will need to see a doctor urgently.

## What do I tell partners about using condoms and being on PrEP?

If you talk about PrEP with your sexual partners, you may find yourself having to teach people about it. This might be difficult sometimes. You can tell people there is information about PrEP at <http://nzprep.org>

It is important for everyone, including those who use condoms, to understand how PrEP works so that they can be able to best protect themselves from getting HIV during sex.

There is no way (unlike when condoms are used) for partners to check if you are on PrEP, or for them to know if you have been taking it correctly. It's important to respect other people's choices; if your sexual partners prefer to use a condom then that's their right.

## Does PrEP change legal requirements about disclosure of HIV?

No. The law around HIV positive people telling their sexual partners they are HIV positive or taking reasonable precautions has not changed. No-one knows if having a sexual partner on PrEP would constitute taking "reasonable precautions," as there have been no legal cases so far to test this.

## How long do I need to take PrEP?

As taking part in this study is your choice (voluntary) you can pull out at any stage if you want to stop taking PrEP. You should always discuss this with your doctor or nurse.

You may decide to stop if:

- If your risk of getting HIV is lower because of changes in your life
- Or if you find you don't want to take a pill every day or often forget to take your pills, other ways of protecting yourself from HIV infection may work better for you.
- You have side effects from the medication that are interfering with your life

If blood tests show that your body is reacting to PrEP in unsafe ways, your doctor may stop prescribing PrEP for you.

***Tell the sexual health clinic staff if you are having trouble remembering to take your medicine or if you want to stop taking PrEP.***

## **If I take part in the study how will my health information be protected?**

Your health information is stored in hospital databases that are password protected and can only be accessed by people looking after your health.

You will be provided with a special unique study number to use when filling out the on-line survey. No other information on your identity will be collected as part of the on-line survey.

Any information published from this study will not identify you as an individual.

## **What Compensation is there if I should get injured as a result of taking part in this Study?**

If you were injured in this study, which is unlikely, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

# Section 2

## Information about Acute HIV Infection and PrEP

### What is acute HIV Infection?

HIV stands for human immunodeficiency virus. This is the virus that causes AIDS. Like other viruses people can often feel unwell when they catch HIV. This is called acute HIV infection.

Symptoms can include:

- A fever
- A tired feeling
- Swollen lymph nodes (also called lymph glands)
- Swollen tonsils (also called tonsillitis)
- A sore throat
- Joint and muscle aches
- Diarrhoea
- A rash

These signs and symptoms can begin a few days after infection with HIV and usually last for about 14 days and then people feel back to normal. However even though the symptoms go away the person still has the HIV virus.

As PrEP does not offer 100% protection it is important to get tested if you have symptoms.

***If you catch HIV while you are on PrEP and you keep taking it, there is a risk you may become resistant to the medication and it could limit your choice of treatment for HIV.***

### What do I do if I think I have acute HIV infection?

- Contact the sexual health clinic as soon as possible on 0800 739 432 and arrange to have a blood test. You will be advised whether you need to stop your PrEP or if it is ok to take it until your test results are back.
- Do not have sex until the test results are back as HIV is very easy to pass on at this early stage.
- If your symptoms occur at the weekend go the nearest hospital emergency department and tell them you are on PrEP so that you are seen by someone who will know what to do.

### What if my HIV test is Positive?

- Don't worry- we will arrange further tests and start you on treatment for your HIV.

***If you have any questions, concerns or complaints about the study at any stage, you can contact:***

Research Nurse: 0800 739 432

***If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:***

Phone: 0800 555 050

Fax: 0800 2 SUPPORT (0800 2787 7678)

Email: [advocacy@hdc.org.nz](mailto:advocacy@hdc.org.nz)

***For Maori Health support please contact:***

Name: Whati Te Wake

Position: Community Engagement Coordinator Maori

Telephone: 09 300 6961

Email: [whati.tewake@nzaf.org.nz](mailto:whati.tewake@nzaf.org.nz)

***You can also contact the health and disability ethics committee (HDEC) that approved this study on:***

Phone: 0800 4 ETHICS

Email: [hdec@moh.govt.nz](mailto:hdec@moh.govt.nz)

***Truvada Medication Information Sheet***

See Medsafe Consumer Medicine Information: <http://www.medsafe.govt.nz/consumers/cmi/t/truvada.pdf>