



# theAlfred

## Participant Information Sheet/Consent Form

### Interventional Study - *Adult providing own consent*

<b>Title</b>	The PrEPX Study
<b>Short Title</b>	PrEPX
<b>Protocol Number</b>	HREC/16/Alfred/16
<b>Project Sponsor</b>	Victorian Department of Health
<b>Coordinating Principal Investigator</b>	A/Prof Edwina Wright (Alfred Hospital)
<b>Site Principal Investigators</b>	A/Prof Edwina Wright (Alfred Hospital) Prof Christopher Fairley (MSHC) Dr BK Tee (Centre Clinic and Access Health and Community Richmond) Dr Norman Roth (Prahran Market Clinic) Dr Richard Moore (Northside Clinic) Dr Jeffrey Willcox (Northside Clinic) Dr George Forgan-Smith (ERA Health) Dr Matthew Penn (Pronto!) Dr Claire Pickett (Ballarat Community Health) Dr Amanda Wade (Geelong Hospital Sexual Health)
<b>Location(s)</b>	<ul style="list-style-type: none"><li>▪ The Centre Clinic</li><li>▪ The Melbourne Sexual Health Centre- HIV Integrated Prevention (HIP) clinic</li><li>▪ Northside Clinic</li><li>▪ Prahran Market Clinic</li><li>▪ PRONTO! Community Health Centre</li><li>▪ ERA Health</li><li>▪ Access Health and Community Richmond</li><li>▪ Ballarat Community Health</li><li>▪ Geelong Hospital Sexual Health</li><li>▪ Alfred Health Nurse-led Clinics</li><li>▪ Alfred Health Outreach Clinics</li><li>▪ Alfred Health- GP Share care clinics</li></ul>



# **Part 1 What does my participation involve?**

## **1 Introduction**

You are invited to take part in this research project. This is because you are HIV-negative and have risk factors for acquiring HIV. The research is testing whether we will see a fall in new HIV infections in Victoria over the next few years, if we provide a new HIV prevention therapy, PrEP, to 2,600 people who are at risk of HIV infection.

PrEP stands for 'pre-exposure prophylaxis' and currently HIV PrEP involves a person taking a daily tablet that contains two HIV antiviral medications, in order to prevent HIV infection. These two antiviral medications are also used to treat people living with HIV infection and people living with chronic hepatitis B infection.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand, or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

When accessing the PrEPX study via Share care with your General Practitioner (GP), the study investigator will perform the consent process remotely via Telehealth by either Skype® or phone, with the GP witnessing you sign the consent.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described

You will be given a copy of this Participant Information and Consent Form to keep.

## **2 What is the purpose of this research?**

In Australia about one thousand people are diagnosed with HIV infection every year and of these, about 300 are diagnosed in Victoria. This number of new annual HIV diagnoses hasn't changed for several years and it is unclear why we can't reduce the number of people becoming infected with HIV.

However the new HIV prevention strategy, PrEP has been shown in a number of clinical trials to be highly effective in preventing HIV infection in gay men, transgender women, heterosexuals and people who inject drugs. The current medication that is used for PrEP is Truvada®, which is

made by Gilead Sciences. Truvada® contains two HIV antiviral medications: Tenofovir and Emtricitabine.

There is evidence that if individuals take PrEP daily that they may reduce their chance of HIV infection by up to 99%. However in some studies PrEP has been less effective at preventing HIV infection. For example in one study of gay men, PrEP only reduced HIV infection by 44% although it reduced HIV by 86% in a different, more recent study. PrEP reduced HIV infection by 70% in studies of heterosexuals and by about 50% in people who inject drugs. The reason why PrEP's ability to prevent HIV infection varies quite a lot between these studies is mostly related to how well people in the studies were able to take (or adhere to) the study PrEP medication. In gay men and heterosexuals there is evidence that taking the PrEP tablets every day reduces HIV infection by 99%. Taking it only a few days a week, or not at all will increase the risk of HIV infection. It is important to note that people who participated in these PrEP clinical trials were also using other HIV prevention strategies as much as possible, including using condoms and having regular tests for sexually transmitted infections and HIV.

Recently the World Health Organisation (WHO), the United States Department of Health and Human Services recommended that all people at high risk of HIV infection should be offered PrEP as part of their HIV prevention options. Australia has also developed recommendations that all people at high risk of HIV infection should be offered PrEP as part of their HIV prevention options.

In the past three years, San Francisco has seen a significant decrease in the number of people with new HIV infections. This decrease in new infections coincides with PrEP becoming widely available in San Francisco during 2013. While there may be other reasons for this fall in new HIV infections in San Francisco, it seems that PrEP may be an important factor in the city's HIV decline.

The purpose of this study is to see whether, by making PrEP available to 2,600 Victorians who are at risk of HIV infection, we can reduce the number of new HIV infections in Victoria by approximately 25% over the next 12- 36 months.

The other reason that we are doing this research is to study what it's like for a large group of people in a community to start taking HIV PrEP. That means we'll be looking at how people's sexual behaviour might change when they take PrEP, how their concerns about acquiring HIV infection might change when they're on PrEP, whether they will take their medications as prescribed and whether they experience more sexually transmitted infections on PrEP. Also we're going to find out whether, if people see their doctor every 3 months for their PrEP prescription, that this means that they might get other health benefits from seeing their doctor, like having their blood pressure treated, or having a skin cancer removed.

This research has been initiated by the study's lead investigator, A/Prof Edwina Wright, and has been funded by the Victorian Department of Health, Alfred Health and the Victorian AIDS Council.

### **3 What does participation in this research involve?**

You will be participating in a research study that examines whether making PrEP available to a large number of Victorians at risk of HIV infection will reduce new HIV infections in Victoria over the next 12-36 months. The duration of the study is twenty-one months.

The majority of study participants will be enrolling in stand-alone sites throughout Melbourne and parts of regional Victoria and this means that the doctor or nurse who enrolls you at these stand-alone sites will manage your care and will follow-up your test results throughout the time that you are on the PrEPX study.

However some study participants will be enrolled and managed at clinics where the enrolment and care is performed in collaboration with study staff from the Alfred Hospital. This will take the form of Outreach clinics or Share care clinics.

If you are enrolling in an Outreach clinic, the only entry that will appear in your local medical records will be that you have enrolled in the PrEPX study.

If you are enrolling in a Share Care clinic, both your local GP and the PrEPX Alfred Clinician will enrol you via Telehealth. Both your local GP and the Alfred clinician will record the history that is obtained during the consultation in the local records and the Alfred records.

By enrolling into this study at an Outreach clinic or a Share care clinic you will become a patient of The Alfred Hospital and you will be allocated an Alfred Hospital unique reference number.

The medical history that the Alfred Hospital PrEPX clinician obtains from you when you enrol in the study will be stored in your Alfred Hospital medical record. Pathology test results will be collected at a local Pathology Service provider close to your clinic. The results will be sent both to the Alfred Hospital and to the Outreach or Share care clinic that you attend. If you require follow-up care from these test results (i.e. you have an STI that needs to be treated) you can be treated at the Outreach clinic or the Share care clinic by your local healthcare provider.

If you transfer to another PrEPX clinic that uses the ACCESS system your future results will become available via the ACCESS system- see below for a more detailed explanation of ACCESS

The study consent form will be signed prior to you having to do any sort of assessments like answering questions, or having blood tests.

Once you have signed the consent form your doctor or another healthcare provider will ask you a number of questions to determine whether you are eligible for the PrEPX study. These will include questions about your sexual preferences and sexual practices, current use of injectable drugs and alcohol, any HIV risk factors over the past three months, any current, or recent symptoms that might resemble acute HIV infection, questions about how healthy your kidneys and bones are and whether or not you are taking medications that can affect how well your kidneys are working. The reason you will be asked these questions about your kidneys and bones is that PrEP can lead to a slight decrease in how well your kidneys function and how strong your bones are- this is discussed in more detail below.

As a PrEPX study participant you may be asked to complete an optional questionnaire that includes questions about your gender, country of birth, sexual behaviour and drug and alcohol use over the previous six months. You will be given an electronic, password -protected tablet (excluding Melbourne Sexual Health Centre) to answer these questions on. Data from these tablets will be stored on the local clinic server and extracted and managed using a secure electronic system.

In addition to the doctor asking you questions, and you filling out the questionnaire, depending on which clinic you go to, we will do blood tests as well. These blood tests are to test whether or not you have HIV, hepatitis B or hepatitis C and we will do blood tests to check your kidney and liver function and a test for protein in your urine. We will also test for sexually transmitted infections by doing a throat swab, a urine test, an anal swab and also a vaginal swab may be required. We will also measure your blood pressure at the first visit.

Following these questions and tests, some participants may be given a PrEP prescription on the same day as the tests are done so that they can commence PrEP straight away. These participants will be considered by their doctor to be very unlikely to have undiagnosed HIV infection, or undiagnosed hepatitis B infection, or undiagnosed kidney problems.

If your doctor gives you a prescription to start PrEP immediately but a day or so later your blood test comes back showing that you might be HIV positive, your doctor will discuss the available options which include ceasing PrEP, or commencing full treatment for HIV infection. If you have started PrEP and are found to have undiagnosed hepatitis B infection you will be advised to remain on PrEP and will be referred to a hepatitis B expert for further evaluation and monitoring. If you are on PrEP but are found to have poor kidney function, your PrEP will be stopped if your kidney function is persistently below 60 mLs per minute and the doctor will discuss other options to minimise your chances of becoming infected with HIV.

You may be advised not to start PrEP until the results of your HIV antibody test, or your hepatitis B test, and/or kidney function tests are available, based upon the best judgement of your doctor. These tests results usually come back within 24-72 hours so the delay in starting PrEP should not be too long.

If you are diagnosed with a sexually transmitted infection after your baseline visit you will be offered treatment, but this will not prevent you from starting the PrEP medication.

During this study we will be providing PrEP which is manufactured in India, by a company called Mylan. Mylan makes their own version, called a 'generic' version of Truvada®. This generic Mylan product contains the same medications as Truvada® (300mg of Tenofovir and 200mg of Emtricitabine) and has the same HIV antiviral properties as Truvada®. The reason for using Mylan's generic Tenofovir and Emtricitabine is because Truvada® is not yet available in Australia for use as HIV PrEP. Truvada® has been registered for use as PREP by the Australian Therapeutic Goods Administration (TGA). If Truvada® then goes on to be approved as a subsidised medication on Australia's Pharmaceutical Benefits Scheme, you will be able to switch to Truvada® and stay on the PrEPX study.

Of note, the study drug is not approved for marketing by the TGA for the purpose of HIV prevention and therefore the use of this Mylan medication for HIV prevention should be considered as experimental.

Mylan's generic version of PrEP is equivalent to Truvada as per an independent report from an expert pharmacologist. This independent report has been made available to the Alfred Hospital Ethics Committee and was prepared by a Professor of Pharmacology at the University of New South Wales. His findings state that all the available data from Mylan show that Mylan's generic version of Truvada is equivalent to patented Truvada®.

Once you have commenced PrEP you will be asked to return every three months to see your doctor. If you are a PrEPX study participant who attends ERA Health, the Alfred HIV integrated prevention clinic Prahran Market Clinic, Centre Clinic, Northside Clinic and PRONTO! and the Melbourne Sexual Health Clinic, you will be asked to complete the same questionnaire you completed at the baseline visit on the electronic tablet.

Also at these three monthly visits you will need to have a blood test for HIV and tests performed to check for sexually transmitted infections. You will be given a new prescription for three months of PrEP at every three-month study visit. At least every six months you will have a blood test and a urine test to evaluate your kidney function. Every 12 months you will have a blood test for hepatitis C infection. We will collect these test results as part of the study.

If you attend the Northside Clinic, ERA Health, the Alfred HIV integrated prevention clinic, the Melbourne Sexual Health Centre HIP Clinic, Prahran Market Clinic, Centre Clinic, or PRONTO! the results of your baseline test results and all your follow-up test results will be obtained via the ACCESS system because these seven clinics all participate in the ACCESS surveillance system, which is run by the Burnet Institute. This means that these seven clinics have given consent for their patients' test results to be collected anonymously for surveillance purposes. In other words, the doctors decided that collecting their patients' test results in an anonymous fashion is a good idea because it contributes to understanding about trends in HIV, sexually transmitted infections and viral hepatitis in Victoria. The ACCESS surveillance system is able to retrieve these test results from the patient management system of the clinics' computers. ACCESS can also get anonymous test results directly from several of the Pathology Laboratories that the PrEPX Study clinics use for their patients' blood tests.

Importantly, however, ACCESS uses software that removes any patient identifying details before the test results are extracted from the clinics' or the pathology labs' computers, thus protecting the patients' privacy. These de-identified test results are sent to the Burnet Institute. However, for the purpose of the PrEPX study, the ACCESS system will use specially designed linkage keys so that we can identify you as a participant in the PrEPX study. This will allow us to follow your test results over time. When we have your identifying details through ACCESS, they will be assigned a code that can only be linked back to you by using a decoding key, which will be stored separately under lock and key and only known to a few members of the research study team (see section 10)

As another part of the PrEPX study, we will also use the ACCESS system to find more about your general health care when you first enter and throughout the study. For patients who enrol in PrEPX at the Northside Clinic, ERA Health, the Melbourne Sexual Health Centre HIP Clinic, Prahran Market Clinic, Centre Clinic, or PRONTO! we will collect data about whether you are on blood pressure tablets, or tablets for your cholesterol, or antidepressants, or whether you are on medications to help you stop drinking alcohol, or to help you quit smoking, or to stop using

drugs. We will also look to see if you have had any skin cancers diagnosed in the past 12 months, or any recent vaccinations. If you have a cervix we will look to see when your last pap smear was and if you're a woman aged 40 years, or older we'll look to see when you had your last mammogram. Finally, if you're over the age of 55 we'll look to see whether or not you've ever had a faecal occult blood test. At 12 months and when the study ends, ACCESS will look at the medical records again of patients at the Northside Clinic, ERA Health, the Melbourne Sexual Health Centre HIP Clinic, Prahran Market Clinic, Centre Clinic, or PRONTO! to see if PrEPX patients have commenced any of the above treatments, or had any of the tests we described in the paragraph above. Study participants attending the Alfred HIP clinic will not have any of this general health information collected at any time. These data will only be collected at ACCESS sites.

We're asking all these general medical questions at the beginning, during and at the end of the study because we want to know whether or not by receiving PrEP, and coming in to see your doctor every three months you will also receive additional health benefits

An optional part of the PrEPX study is to do an on-line survey at baseline and every six months during the study. We are asking 10%, or 260 people in the PrEPX study to do this. The on-line survey is confidential and won't be shared with your doctor. The survey asks you questions about how you are feeling about being on PrEP, what your sexual behaviour is like on PrEP, what your adherence to the PrEP medications is like and similar questions. It will take about 15 minutes.

We will also ask 30 study participants to participate in in-depth, face-to-face interviews at the beginning of the study and at the end of the study. These will take approximately one and a half hours and you would be asked questions about your personal experiences of being a person taking PrEP. The face-to-face interviews will take place in a private office at The Burnet Institute.

#### Additional costs & reimbursement

You will not be paid for participating in this project. As this study is designed to reflect the real world experience, you will be required to pay what would be the regular cost of a government subsidised prescription for PrEP if PrEP was really available. The cost will be the current PBS co-payment for concession cardholders and for non-concession cardholders, every 3 months.

You will be able to have your prescription filled at either 1) Alfred Clinical Trials Pharmacy at The Alfred Hospital 2) The Healthsmart Pharmacy at The Alfred Hospital, 3) the Melbourne Sexual Health Centre Pharmacy, 4) Silverii's pharmacy near the Northside clinic, 5) the Prahran Central Pharmacy near Prahran Market Clinic, 6) the Russel Frajman Pharmacy near Centre Clinic and 7) the Newton and Leung Pharmacy near PRONTO!

For participants attending an Outreach clinic or a Share care clinic in rural and regional Victoria there are two options around how your script can be dispensed: (1) the Alfred Hospital Clinical Trials Pharmacy, in Melbourne can send the PrEP medication to you via mail in plain packaging. The package will contain an invoice, which you will need to pay via BPAY or another method listed on the invoice. The first time that the pharmacists at the Alfred Hospital Clinical Trials Pharmacy send you your PrEP medication they will phone you first to discuss the medications and their potential side-effects, how to take the medication and they are likely to ask you about any other medications that you are currently taking. They need to make this phone call to

ensure your safety. (2) If you are travelling to Melbourne, you will be able to have your prescription filled at any of the seven pharmacies listed above.

It's an unusual thing to ask you to pay for study medications in a clinical trial, but we need to accurately reflect the 'real world situation' in this study because in the future, PrEP users will have to pay a co-payment for their PrEP medication if Truvada® is listed on the PBS.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

#### **4 What do I have to do?**

Participation in this study does not require any restrictions to your diet or your participation in sports. It is not anticipated that participation will affect any other medications you may be taking, however, it is important let the study doctor know any other medications you are taking in particular if you are taking simple painkillers like Nurofen or Ibuprofen which can affect the kidneys. Consenting to PrEP requires taking the study medication daily, in accordance with the instructions provided. We encourage you to use safer sex practices as best as possible including use of condoms, sexual positioning and serosorting with any regular or casual partners and to attend every 3 months for your HIV testing and testing for sexually transmitted infections.

#### **5 Other relevant information about the research project**

A total of 2,600 Victorians who are HIV-negative and have risk factors for acquiring HIV will participate in this study. Recruitment into The PrEPX Study is open to all people who are HIV-negative and have risk factors for HIV acquisition, regardless of gender or sexual preference.

There are **ten** sites involved in the project: The Centre Clinic, Melbourne Sexual Health Centre HIP clinic, Prahran Market Clinic, Northside Clinic, PRONTO!, the ERA Health in Bourke Street Melbourne, Access Health and Community Richmond, Ballarat Community Health, Geelong Hospital Sexual Health and The Alfred Hospital HIP clinic including outreach clinics at:

- Central Gippsland Health Service Sale Hospital 155 Guthridge Parade, Sale
- Mildura Base Hospital Ontario Ave and Thirteenth Street Mildura
- Joslin Medical Centre Cohealth 575a Barkly St Footscray
- Sexual Health and Reproductive Services Bendigo Community Health Services LTD Central Bendigo 171 Hargreaves St Bendigo
- Other GPs yet to be negotiated with share care arrangements

Participants attending clinics outside of metropolitan Melbourne may receive study drug dispensed from Alfred clinical trials pharmacy and then posted to the participant or their GP for collection.

Participants who enrol via Outreach Clinics and via Shared care with their local GP and Alfred Health will have PrEPX study participation recorded in both medical records.

The principal investigator for this project is A/Prof Edwina Wright. The Alfred Hospital Clinical Research Team is responsible for the day-to-day management and coordination of the study. Members of this team include the Principal Investigator and investigators from The Alfred Hospital and all participating clinics.

#### **6 Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with The Alfred Hospital or your GP clinic.

## **7 What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at this clinic. Other options are available; these include advice and counselling on safe sex practices and the benefits of regular HIV and STI testing and discussion about the option of using HIV post-exposure prophylaxis (PEP) after any sexual or injecting exposures that may have put you at risk of acquiring HIV infection. Also there is the option of exercising your right to import PrEP medications for personal use. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss these options with your local doctor.

PrEP is currently available on private prescription outside of this study, at a cost of approximately A\$800 per month, regardless of concession benefits.

## **8 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include reducing your chances of becoming infected with HIV. Research shows that taking PrEP every day, combined with use of safer sex practices including use of condoms, is associated with a significantly decreased risk of HIV infection in MSM, transgender people, heterosexuals and people who inject drugs, compared to not taking PrEP medication.

## **9 What are the possible risks and disadvantages of taking part?**

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about which may be serious. Tell your study doctor immediately about any new or unusual symptoms that you experience.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. Your study doctor will discuss with you the best way of managing any side effects you may experience.

In people who are HIV-negative, the most commonly reported side effects of Tenofovir and Emtricitabine when given as PrEP are headache, back pain, abdominal pain, unintentional weight loss, nausea, flatulence, abdominal pain. In a recent study of people commencing PrEP, these symptoms were reported before PrEP was started by 22% of participants but this number increased to 39% after one month of PrEP. However these symptoms resolved over the following 12 weeks.

PrEP (Tenofovir and Emtricitabine) has been associated with a small decline in the health of the kidneys, but this decrease is not likely to be clinically significant. A decline in the health of the kidneys may be more likely in older people and people with high blood pressure, or diabetes, or people who already have some mild kidney disease. Once PrEP is stopped, studies have shown that the kidneys return to normal. Your doctor will be performing blood tests at the beginning of the study to check your kidneys before you start and every six months while you are taking PrEP. In some cases your doctor may want to check your kidneys more frequently than every six months. Your study doctor may tell you to stop taking PrEP if you develop kidney problems during the study.

PrEP (Tenofovir and Emtricitabine) has also been associated with a small decline in the strength of the bones, but this decrease is not likely to be clinically significant. Your doctor may suggest that you have some tests to check your bone health before starting you on PrEP especially if you are older, if you have diabetes, or take steroid tablets, or have chronic health problems. Once PrEP is stopped, studies have shown that the bones return to normal.

Overall, we know that if Tenofovir and Emtricitabine is used by a person for one to three, or four years, overall it's a safe HIV prevention method. However, we do not know a lot yet about side effects for people who take PrEP for longer periods of time. And we don't know whether taking Tenofovir and Emtricitabine for a few years causes any health problems in 10, 20, or 30 years' time.

In February 2016, a case was reported of a person becoming infected with HIV despite having evidence that they were taking Truvada® for PrEP on a daily basis. This is the only known case where Truvada® for PrEP has truly failed. It is understood that the reason that it failed was that the person was infected with a strain of HIV that was resistant to Truvada®. In Victoria we have records of the number of people who have been infected with a drug-resistant strain of HIV. Between 1996 and 2007 the number of people who were infected with a strain of HIV that could potentially have overcome Truvada was very low at approximately 1.0%. In another study of people from all around Australia, only 0.3% or one in 300 people had HIV mutations that could potentially have overcome Truvada. So the risk of being infected with a strain that is resistant to Tenofovir and Emtricitabine is very low, but not zero. This is a reason to consider trying to use condoms as regularly as possible.

If you do become infected with HIV during this study your doctor will discuss with you the benefits of ceasing PrEP and either not starting any HIV treatment for the time being, or switching to HIV treatment that may or may not contain generic Tenofovir + Emtricitabine with the aim of providing rapid and complete suppression of HIV. In this setting, in addition to standard of care, we will also take a small sample of blood to test your PrEP drug levels to see if they were protective against HIV infection (research only). In all cases, your doctor will discuss your recent HIV infection with an HIV specialist to optimise the best possible management of your health.

If you become pregnant whilst participating in the PrEPX study, you should advise your study doctor immediately. Your study doctor will withdraw you from the research project and advise on further medical attention, should this be necessary. You must not continue in the research project if you become pregnant.

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

Having a blood sample taken may cause some discomfort or bruising. Sometimes, the blood vessel may swell, or blood may clot in the blood vessel, or the spot from which tissue is taken could become inflamed. Some people may feel faint when having blood taken, and may occasionally faint. Rarely, there could be a minor infection or bleeding. If this happens, it can be easily treated.

## **10 What will happen to my test samples?**

If you are enrolling at a PrEPX Outreach clinic or a PrEPX Share care clinic, as described above, your tests will be done by a local pathology provider and the results of the tests will be sent to your local clinic where you enrolled into PrEPX and also to your records at The Alfred Hospital.

If you enrol through a clinic that uses the ACCESS system your test samples will be re-identifiable, that is a unique study code will be assigned to your sample. The code can only be linked back to you by using a decoding key, which will be stored separately under lock and key and only known to a few members of the research study team.

The routine blood tests include a test for HIV, sexually transmitted infections, hepatitis B virus and hepatitis C virus. This is because the study doctors need to ensure that you are both HIV-negative and needs to know if you have viral hepatitis. You will receive information and counselling before the test. If a test shows you have HIV or Hepatitis, you will have follow-up counselling and appropriate medical advice. If your test results are positive, the study doctors are required by law to notify government health authorities. Signing the consent form means that you agreed to have this testing; it will not be done without your consent. All test samples collected for the purpose of this study will be destroyed after analysis, as per routine laboratory practice.

## **11 What if new information arises during this research project?**

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interest to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

## **12 Can I have other treatments during this research project?**

It is not anticipated that your participation will affect any other medications you may be taking with the exception of medications that can affect your kidney function. However, it is important to let the study doctor know about any other medications, or treatments you may be taking and/or using, including over-the-counter medications, vitamins or herbal remedies, acupuncture

or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor will explain to you which treatments or medications need to be stopped for the time you are involved in the PrEPX study.

### **13 What if I withdraw from this research project?**

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research can be measured properly, and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want this to happen, you must tell the researcher before you join the PrEPX study.

### **14 Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable side effects
- The treatment being shown not to be effective
- The treatment being shown to work and not need further testing
- Decisions by local regulatory/health authorities

### **15 What happens when the research project ends?**

Generic Tenofovir and Emtricitabine for use as PrEP will be made available to you during the study for 21 months. Truvada® has been registered by the TGA and it is being evaluated by the Pharmaceutical Benefits Advisory Committee to determine whether the government will subsidise the cost of Truvada® for use as PrEP. If this happens you can stay in the PrEPX study until drug supply is exhausted, or you may choose to switch to the licensed drug Truvada® which your doctor can prescribe for you. When the study ends it is possible that Truvada® will be subsidised for use as PrEP by the PBS. In this case you can continue to receive a regular prescription for PrEP from your GP after the study has finished and the pharmacy will dispense Truvada®. We are unable to guarantee that you will receive PrEP after the PrEPX study has finished.

We anticipate that all participants in the study will have completed the study by mid to late 2018. All the data will be analysed and a one-page summary of results will be prepared for participants. Study staff will send copies of the summary to each participating clinic and you will be given the summary at your next routine clinic visit with your doctor.

## **Part 2      How is the research project being conducted?**

### **16      What will happen to information about me?**

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential.

When you enrol in the PrEPX study, the study team will have access to your medical record number from the clinic where you enrolled in the study, the name of the clinic where you enrolled, the first two letters of your first name and surname and your date of birth. In addition, we require your email address and if this has your name in it, that means we could directly identify you. Your year of birth, clinic medical record number and clinic site of enrolment will be provided to the ACCESS project based at the Burnet institute so that your test results and health information can be extracted and analysed for the duration of the PrEPX study. We need to collect the letters from your name and your full year of birth to be able to help people transfer between clinics easily. Staff working at the Burnet will not have access to identifiable data records only coded data.

Information will be stored and analysed using a study-specific password-protected database (PrEPX database), in a locked office to which only members of the study team will have access. Any identifiable information about you (for example, your medical record number from your clinic) will be stored at the participating clinics and on the PrEPX database, only for the purpose of verification, and any paper based forms will be stored in a locked office, which only the members of the study team can access. Your information will only be used for the purpose of this research, and it will only be disclosed with your permission, except as required by law.

You will be assigned as unique study code when you enter the study, this code will be used to protection your information when it is being analysed during and at the end of the study. Information about your participation in this research project will be recorded in your health records. Study files will be archived in a locked storage facility and kept indefinitely, as per Alfred Health policy. Coded data in electronic form will also be stored indefinitely.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

This research project also involves the collection of information about your use of drugs. In the event that Alfred Health is required to disclose that information, it may be used against you in legal proceedings or otherwise.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. Data will be coded and grouped for publication/presentation.

In accordance with relevant Australian and Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree, be corrected. Please contact the study team member named at the end of this document if you would like to access your information. Any information obtained for the purpose of this research project and

for any future related research described in Section 16 that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

## **17 Injury**

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. Because you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

## **18 Who is organising and funding the research?**

This research project is being conducted by the Principal Investigator, A/Prof Edwina Wright and is being funded by the Victorian Department of Health, Alfred Health and the Victorian AIDS Council.

The Alfred Hospital will receive a payment from the Victorian Department of Health for undertaking this research project. No member of the research team will receive personal financial benefit from your involvement in this research project (other than their ordinary wages).

## **19 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of the Alfred Hospital. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

## **20 Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal investigator- A/Prof Edwina Wright on 9076 6078 or any of the following people:

### **Melbourne Sexual Health Centre, HIV Integrated Clinic**

Name	Professor Christopher Fairley
Position	Director
Telephone	9341 6236
Email	cfairley@unimelb.edu.au

### **Northside Clinic**

Name	Dr Richard Moore
Position	Director
Telephone	9485 7700
Email	richard.moore@northsideclinic.net.au

### **Centre Clinic**

Name	Dr Ban Kiem Tee
------	-----------------

Position Director  
Telephone 9525 5866  
Email bk\_tee@vic aids.asn.au

**Prahran Market Clinic**

Name Dr Norman Roth  
Position Director  
Telephone 9514 0888  
Email norm@prahranmarketclinic.com

**Alfred HIV Integrated Prevention Clinic, Nurse-led clinics, Outreach clinics and Share care**

Name Dr Christina Chang  
Position Physician  
Telephone 9076 2000 / 0429473138  
Email prepx@alfred.org.au

**PRONTO! Community Health Centre**

Name Dr Matthew Penn  
Position Physician  
Telephone 9416 2889  
Email Matt.penn@vac.org.au

**ERA Health, Bourke Street, Melbourne**

Name Dr George Forgan-Smith  
Position Physician  
Telephone 9944 6200  
Email georgeforgansmith@erahealth.com.au

For matters relating to research, please contact the study co-ordinators:

Name Mr Timmy Lockwood  
Position Study Investigator  
Telephone 9076 3981/ 0429 473 138  
Email J.Lockwood2@alfred.org.au

Name Mr Brian Price  
Position Study Investigator  
Telephone 9076 3981 / 0404 816 429  
Email b.price@alfred.org.au

**Ballarat Community Health, Lilbourne Street, Ballarat**

Name Dr Claire Pickett  
Position Physician  
Telephone 5338 4540  
Email clairep@bchc.org.au

**Access Health and Community, Church Street, Richmond**

Name Dr Ban Kiem Tee  
Position Physician

Telephone 9429 1811  
Email bk.tee@vac.org.au

**Geelong Hospital Sexual Health, Geelong University Hospital**

Name Dr Amanda Wade  
Position Physician  
Telephone 4215 1396  
Email amanda.wade@icloud.com

**Complaints contact people:**

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Position Research Governance Officer-Alfred Health  
Telephone 9076 3619\*  
Email [research@alfred.org.au](mailto:research@alfred.org.au)

\* You will need to tell him/her the following Alfred Health Project Number: 100/16

Name Mr Timmy Lockwood  
Position Study Investigator  
Telephone 9076 3981 / 0429 473 138  
Email J.Lockwood2@alfred.org.au

## Consent Form - *Adult providing own consent*

<b>Title</b>	The PrEPX Study
<b>Short Title</b>	PrEPX
<b>Protocol Number</b>	HREC/16/Alfred/16
<b>Project Number</b>	100/16
<b>Project Sponsor</b>	Alfred Health
<b>Coordinating Principal Investigator/ Principal Investigator</b>	A/Prof Edwina Wright
<b>Locations</b>	Centre Clinic, Melbourne Sexual Health Centre HIV Integrated Prevention Clinic, Prahran Market Clinic, Northside Clinic, Era Health, PRONTO! and The Alfred Hospital HIV Integrated Prevention Clinic

### **1) Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release coded information to Alfred Health concerning my health status and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____
Signature _____ Date _____

### **Declaration by Study Doctor/Senior Researcher<sup>†</sup>**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher <sup>†</sup> (please print) _____
Signature _____ Date _____

<sup>†</sup> A senior member of the research team must provide the explanation of, and information concerning, the research project.

**Note: All parties signing the consent section must date their own signature.**

I consent to the storage and use of blood samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for this specific research project only.

**2) Declaration by Participant: consent to try and optimise my use of safer sex practices while taking PrEP**

I agree to try and optimise my safer sex practices, including the use of condoms, as described in Sections 3 and 4 of the Participant Information Sheet.

YES       NO

**3) Declaration by Participant: consent to regular STI testing while taking PrEP**

I agree to have regular HIV and STI testing as described in Sections 3 and 4 of the Participant Information Sheet, and as recommended by the study doctor

YES       NO

**4) I consent to participating in the online study surveys**

YES       NO

**5) I consent to participating in the face-to-face in-depth interviews**

YES       NO

**6) I currently have a valid Medicare card**

YES       NO

Name of Participant (please print) \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

Name of Study Doctor/  
Senior Researcher<sup>†</sup> (please print)

Signature \_\_\_\_\_ Date \_\_\_\_\_

<sup>†</sup> A senior member of the research team must provide the explanation of and information concerning the research project.

**Note: All parties signing the consent section must date their own signature.**

## Form for Withdrawal of Participation

**Title:** The Pre-exposure Prophylaxis Expanded (PrEPX) Study

**Short Title:** PrEPX

**Protocol Version:** October 4, 2016. Version 5.0

**Protocol Number:** HREC/16/Alfred/16

**Project Sponsor:** The Alfred Hospital, Melbourne

**Coordinating Principal Investigator:**

Associate Professor Edwina Wright, Department of Infectious Diseases, Alfred Hospital and Monash University

**Co- Investigator(s):**

Mr Brian Price; Associate Professor Mark Stoove; Mr Simon Ruth; Mr Colin Batrouney; Mr Michael West; Dr Dean Murphy; Professor John de Wit; Ms Luxshimi Lal

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with [insert clinic/Institution].

Name of Participant (please print) \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

In the event that the participant's decision to withdraw is communicated verbally, the Clinician/Senior Researcher will need to provide a description of the circumstances in the participant's source documentation.

**Declaration by Investigator /Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Investigator/Senior Researcher† (please print): \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.