



## Participant Information Sheet/Consent Form

**Interventional Study - Adult providing own consent**

<b>Title</b>	The Victorian Pre-Exposure Prophylaxis Demonstration Project
<b>Short Title</b>	The VicPrEP Study
<b>Project Number</b>	564/13
<b>Project Sponsor</b>	Victorian Department of Health
<b>Coordinating Principal Investigator/ Principal Investigator</b>	A/Prof Edwina Wright (Alfred Hospital)
<b>Associate Investigator(s)</b>	Prof John De Witt (UNSW) Mr Dean Murphy (UNSW) Ms Luxi Lal (Alfred Hospital/Burnet Institute) Dr Jennifer Audsley (Alfred Hospital) Prof Christopher Fairley (MSHC) Dr Timothy Read (MSHC) Ms Julie Silvers (MSHC) Dr B K Tee (Centre Clinic) Ms Danielle Collins (Centre Clinic) Dr Norman Roth (Prahran Market Clinic) Ms Helen Lau (Prahran Market Clinic & Centre Clinic) Dr Richard Moore (Northside Clinic) Dr Jeffrey Willcox (Northside Clinic) Ms Rachel Wolstencroft (Northside Clinic) Ms Sian Edwards (Northside Clinic) A/Prof Michelle Giles (Alfred Hospital /Royal Women's)
<b>Location</b>	Centre Clinic, Melbourne Sexual Health Centre, Prahran Market Clinic and Northside Clinic

## **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 project is testing the use of anti-HIV medicines, used in treating people with HIV, as a way to reduce the chance of becoming HIV-positive in people who are HIV-negative. This is called pre-exposure prophylaxis, or PrEP for short.

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.

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?**

Medications, drugs and devices have to be approved for use by the Australian Federal Government. Truvada (tenofovir and emtricitabine) is approved in Australia for HIV management in people who are HIV-positive. However it is not approved in Australia to reduce the risk of HIV transmission in people who are HIV-negative. Therefore, it is an experimental treatment for reducing the risk of HIV transmission in HIV-negative people. This means that it must be tested to see if it is an effective method for reducing the risk of HIV transmission. Truvada has been recently approved by the FDA in the United States for PrEP in people who are HIV-negative.

New HIV prevention strategies are necessary in Australia because HIV infection rates continue to rise. HIV pre-exposure prophylaxis (PrEP), when given as a daily pill and coupled with the consistent use of condoms and regular checks for sexually transmitted infections including HIV, is effective in preventing HIV infection. Several overseas studies have shown that daily tenofovir, or daily Truvada (tenofovir and emtricitabine) reduces HIV transmission by about 44% in men who have sex with men (MSM) and by about 70% in heterosexual people at risk of becoming HIV positive. There has been further evidence to show that in MSM who take their Truvada PrEP medication in the prescribed manner, that is one pill every day, that their risk of HIV infection is reduced by 96%. So taking PrEP every day according to the instructions along with using HIV prevention measures like condoms and regular HIV and sexually transmitted infection (STI) screening is the best way to reduce your chances of becoming infected with HIV.

It is now important to examine the results of these PrEP clinical trials in the "real world" setting to show that PrEP is a feasible, safe and effective method for reducing the risk of HIV

acquisition in the Victorian community. The VicPrEP demonstration project will address this need.

This research has been initiated by the study doctor, A/Prof Edwina Wright, and has been funded by the Victorian Department of Health. Gilead Sciences, the manufacturer of Truvada, are supporting the study by providing the study drug.

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

You will be participating in a demonstration study examining the feasibility of PrEP to reduce the risk of HIV transmission in HIV-negative people with risk factors for acquiring HIV. Your involvement with the study will last two years. The overall study will run for a maximum of four years, with a two-year period for recruitment and a further two years for all participants to complete the study. If you consent to the study, you have the option of taking or refusing use of PrEP.

**If you additionally consent to take PrEP**, the VicPrEP study will collect for a period of up to 12 months clinical information that relates to your sexual behaviour and health and how well you tolerate and take your Truvada treatment. For a total period of 24 months from study entry period we will have access to your behavioural surveys and STI test results that you usually complete at your clinic because you attend a clinic that participates in the Victorian Primary Care Network for Sentinel Surveillance on Blood Borne Viruses and Sexually Transmitted Infections (VPCNSS). VPCNSS is set up to monitor sexual behaviour and HIV and STI testing among priority populations). If your clinic does not participate in the VPCNSS then you will be asked to complete a tick-box behavioural survey. Consenting to PrEP requires taking a tablet of Truvada, orally, once a day. The tablet contains 200mg of Emtricitabine and 300mg of Tenofovir. During this time you will continue to be treated as usual by your treating physician and he/she will make any decisions regarding your treatment that are required. The consent form will be signed prior to any study assessments being performed. Your information will be screened to make sure you are eligible for the study, such as risk factors for HIV transmission and no evidence of hepatitis B virus infection. Information will be collected from you and your doctor when you first join, and then at regular 3-monthly study visits whilst taking PrEP, for a maximum of 12 months. At each of these clinic visits your doctor will ask about your health, your use of study medications and your sexual practices including safer sex practices. During the 12-month period you may elect to stop the PrEP medication if you perceive that you no longer need it. Your doctor will discuss with you how to plan to stop PrEP during the study period if you need to. All participants are required to complete an on-line questionnaire (taking approximately 20 minutes) after you join the study, and every 3 months around the time of the study visit to your doctor while you are taking PrEP (these will take approximately 10-15 minutes). We will ask some specific questions about you, such as age, gender, education and relationships, sexual practices and behaviour. We will also ask about your beliefs and attitudes to HIV and its prevention and your experience with PrEP. We will also ask about how often you take your study medications in these on-line questionnaires. None of your survey answers will be shared with your doctor because the study researchers are using the answers from these surveys to examine how PrEP influences peoples' lives at a population level, not at an individual level. Each study visit will add approximately 15 minutes to your regular standard of care clinic visit. There will be a total of 4 study visits after the study entry visit, that is every 3 months for one year. At each of these visits you will have an HIV antibody test and tests for sexually transmitted infections. You will have blood samples taken as part of routine care, and we will use about 5 drops of blood from your blood test sample to test the presence of study drug in your blood. This will tell the study researchers about how study participants took Truvada according to the instructions. Your doctor will not be given the results of your drug level blood tests because the study researchers are using this test to examine the use of PrEP in the study group as a whole, not to examine how often an individual uses their PrEP medication.

You will also be asked for optional consent to be included in the process of random allocation from a small number of participants (about 20 people) for two in-depth face-to-face interviews regarding your experience and use of PrEP, and to evaluate and provide feedback on the study. The first interview will be held after you have taken PrEP for about a month and the second about 12 months later. The interviews take about one hour. After you have finished taking PrEP for 12 months, or less we will access your behavioural survey data and HIV and STI testing results that are obtained through VPCNSS for a total period of 24 months after you first commenced the PrEP medication. We will access your VPCNSS results during the study.

**If you choose to accept PrEP as part of your participation in the VicPrEP study:**

- You will be expected to take Truvada every day, as per the instructions
- You will be expected to practice safe sex, including consistent use of condoms
- You will have regular STI testing, at each study visit and as needed between study visits.

**If you wish to participate, but do not consent to taking PrEP**, the VicPrEP study will collect clinical information that relates to your sexual health at study entry for a period of 24 months from study entry we will have access to your behavioural surveys and STI test results that you usually complete at your clinic because you attend a clinic that participates in the The Victorian Primary Care Network for Sentinel Surveillance on Blood Borne Viruses and Sexually Transmitted Infections (VPCNSS). If your clinic does not participate in the VPCNSS then you will be asked to complete a tick-box behavioural survey. We will access your survey and STI testing results through VPCNSS, which is set up to monitor HIV and STI testing among priority populations. We will access your VPCNSS results during the study. All participants are required to complete an on-line questionnaire (taking approximately 20 minutes) after you join the study.

The purpose of asking study participants who do and do not use PrEP to consent to us following up their behavioural survey data and HIV and STI testing results through VPCNSS is to see whether using PrEP versus not using PrEP is associated with a decreased behaviour risk and decreased HIV and STI infections in the future.

Additional costs & reimbursement

You will not be paid for participating in this project. The VicPrEP study is investigating how effective PrEP will be in the real world. Therefore, you will be required to pay what would be the regular cost of Truvada, if it was available as PrEP. The cost is \$5.90 for concession cardholders or \$36.10 for non-concession cardholders every 3 months, according to hospital/clinic policy. You will be required to have your prescription filled at either 1) Alfred Hospital Clinical Trials Pharmacy or 2) Melbourne Sexual Health Pharmacy. This is an unusual thing to ask patients do to in a clinical trial but we need to truly reflect the 'real world' in this study because future PrEP users in Victoria will have to pay for their PrEP medication.

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. Consenting to PrEP requires taking Truvada daily, in accordance with the instructions provided, and the continued use of safer sex practices including use of condoms with any regular or casual partners and regular STI and HIV testing.

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

A total of 200 people who are HIV-negative and have risk factors for acquiring HIV will participate in this project over a period of four years: 100 who accept the use of PrEP and 100 who decline PrEP. VicPrEP study recruitment is open to all people who are HIV-negative and have risk factors for HIV acquisition, regardless of gender or sexual preference. There are five sites involved in the project: Centre Clinic, Melbourne Sexual Health Centre, Prahran Market Clinic, Northside Clinic and the Chronic Viral Illness Clinic at the Royal Women's Hospital. The principal investigator for this project is A/Prof Edwina Wright. The VIC PrEP Study Management 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, Burnet Institute, Melbourne, and University of New South Wales Centre for Social Research in Health.

## **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. 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.

Truvada is currently available on private prescription, for use as PrEP outside of this study, at a cost of A\$800 per month, regardless of Health Care Card status.

## **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 Truvada 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 and heterosexuals, compared to taking it less than every day.

## **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 Truvada are headache, back pain, abdominal pain, unintentional weight loss and nausea. These were reported in less than 5% of the participants. In people who are HIV-positive, the most common (reported in 10% and greater) side effects are diarrhoea, nausea, fatigue, headache, dizziness, depression, insomnia (sleeplessness), abnormal dreams, and rash. Worsening of kidney function, decrease in bone minerals, changes in body fat, build-up of lactic acid in the blood and enlarged liver, have been reported in people who are HIV-positive and taking Truvada. In studies of PrEP those study participants who were receiving the active study drug (either Truvada or tenofovir) versus those who were receiving placebo were significantly likelier to have nausea, unintentional weight loss, dizziness, back pain and a loss of bone mineral density.

If you have had kidney problems in the past or need to take another medicine that can cause kidney problems, your doctor will be performing blood tests at the beginning of the study to check you kidneys before you start and while you are taking Truvada. Your study doctor may tell you to stop taking Truvada if you develop kidney problems during the study.

Bone problems can happen in some people who take Truvada. Bone problems include bone pain, softening or thinning (which may lead to fractures). Your study doctor may need to do some tests to check your bones.

The effects of Truvada on an unborn child and on a newborn baby are not known. Because of this, it is important that research project participants are not pregnant or breast-feeding, and do not become pregnant during the course of the research project. You must not participate in this study if you are pregnant or breast-feeding. If you are female and childbearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the VicPrEP study. If you are male, you should not father a child or donate sperm for at least 12 months after the last dose of study medication. All participants are expected to continue use of safer sex practices, including use of condoms.

If you do become pregnant whilst participating in the VicPrEP 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?**

The blood taken from your standard of care blood sample will be used to drop 5 spots onto a piece of cardboard and stored for testing at the Burnet Institute (Prof Suzanne Crowe's WHO certified laboratory). Access to part of your routine clinic blood sample is required for the purposes of the VicPrEP study. The dried blood spot samples will be used to test the amount of Truvada present in your blood. A small number of samples (no more than 10%) will be selected at random and sent to the United States (University of Colorado, Denver) for quality

control verification purposes. This study will not provide information about your future health or risk of having children with a genetic disorder, or information that may be relevant to the health of family members who are not part of the study. Sometimes, one or two of the dried blood spots may be left over after testing, and these will be stored indefinitely. Additional testing may be performed on stored samples at a later date for this, or other related research. In future, should we wish to proceed with further testing of any stored blood samples, testing will have to be approved by an Independent Ethics Committee. You will not be re-contacted to obtain consent for this testing to occur.

Your 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. All samples will be re-identifiable for assessment of study drug adherence.

Samples of your blood (in the form of a dried blood spot) obtained for the purpose of this study will be transferred to The Burnet Institute for analysis of the level of Truvada present.

The routine blood tests include a test for HIV and hepatitis B virus (HBV). This is because the study doctors need to ensure that you are both HIV-negative and HBV negative. 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 agree to have this testing; it will not be done without your consent.

#### **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. However, it is important let the study doctor know 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 VicPrEP 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 VicPrEP 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?**

If you consent to take PrEP, it will be available to you for 12 months during the study. After this time the treatment will not be available, as it has not yet been approved by the TGA in Australia for lowering the risk of HIV transmission in people who are HIV-negative.

We anticipate that all participants in the study will have completed the study by March 2018. All the data will be analysed and a one-page summary of results will be prepared for all 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. Information will be stored and analysed in a coded format using a study-specific password-protected database (VicPrEP database), in a locked office to which only members of the study team will have access. Any identifiable data will be stored separately 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 or other related research, and it will only be disclosed with your permission, except as required by law. Coded data may be used in future related research. You will be assigned as unique study code when you enter the study, this code will be used to identify your information. This is a re-identifiable format; that is the code can be linked back to you only by using a decoding key, which will be stored separately under lock and key. The information will be re-identifiable for the assessment of study drug adherence. Information about your participation in this research project may 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.

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 Complaints and compensation**

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. If 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. The manufacturer of Truvada, Gilead Sciences, is supporting the project by providing the study drug.

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**

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@vicaids.asn.au](mailto:bk_tee@vicaids.asn.au)

**Prahran Market Clinic**

Name Dr Norman Roth  
 Position Director  
 Telephone 9514 0888  
 Email [norm@prahranmarketclinic.com](mailto:norm@prahranmarketclinic.com)

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

**Complaints contact people:**

Name Ms Luxi Lal  
 Position Study Co-ordinator  
 Telephone 9282 2260/ 0413 312 439  
 Email [luxshimi@burnet.edu.au](mailto:luxshimi@burnet.edu.au)

Name Dr Jennifer Audsley  
 Position Study Co-ordinator  
 Telephone 9076 9042  
 Email [jennifer.audsley@monash.edu](mailto:jennifer.audsley@monash.edu)

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:

**Reviewing HREC approving this research and HREC Executive Officer details**

Reviewing HREC name	Alfred Health
HREC Officer	Ms Emily Bingle Research Governance Officer, Office of Ethics & Research Governance, Alfred Health
Telephone	(03) 9076 3619*
Email	<a href="mailto:research@alfred.org.au">research@alfred.org.au</a> *

\* You will need to tell Ms Bingle the following Alfred Health **Project Number: 564/13**

## Consent Form – VicPrEP *Adult providing own consent*

<b>Title</b>	The Victorian Pre-Exposure Prophylaxis Demonstration Project
<b>Short Title</b>	The VicPrEP Study
<b>Protocol Version</b>	3.0, dated Dec 9, 2013
<b>Project Sponsor</b>	Victorian Department of Health
<b>Coordinating Principal Investigator/ Principal Investigator</b>	A/Prof Edwina Wright
<b>Location</b>	Centre Clinic, Melbourne Sexual Health Centre, Prahran Market Clinic and Northside 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 information to the University of New South Wales- Centre for Social Research in Health concerning my disease 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 understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

**2) Declaration by Participant: consent to in-depth interview**

I consent to be included in the random allocation for an in-depth interview, as described in Section 3 of the Participant Information Sheet.

YES  NO

**3) Declaration by Participant: consent to PrEP**

I consent to taking PrEP (Truvada) every day, as described in Sections 3 and 4 of the Participant Information Sheet.

YES  NO

**4) Declaration by Participant: consent to continue use of safe sex practices while taking PrEP**

I agree to continue using safe sex practices, including the use of condoms, as described in Sections 3 and 4 of the Participant Information Sheet.

YES  NO  N/A because I will not be taking PrEP

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

I agree to having 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  N/A because I will not be taking PrEP

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

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

Name of Witness\* to  
Participant's Signature (please print) \_\_\_\_\_

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

\* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

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.**