# Participant Information and Consent Form

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| Title | The Queensland Pre-Exposure Prophylaxis Demonstration Project Second Expansion |
| Short Title | The QPrEP Study "QPrEPd-X" |
| HREC Number | HREC/14/QGC/182 |
| Project Sponsor | Cairns and Hinterland Hospital and Health Service |
| Chief Investigator | A/Prof Darren Russell |

Associate Investigators Monitoring and Evaluation (UQ School of Public Health)

- Prof Charles Gilks
- Dr Lisa Fitzgerald
- Dr Owain Williams
- Dr Judith Dean
- Ms Melissa Warner

Associate Investigators at Study Locations

- Dr David Orth (Gladstone Road Medical Centre)
- Dr Maree O'Sullivan (Gold Coast Sexual Health Service)
- Dr Kuong Tiang (Sunshine Coast Sexual Health and HIV Service)
- Dr Arun Menon (Townsville Sexual Health Service, Mt Isa Sexual Health Service & Mackay Sexual Health and Sexual Assault Service))
- Dr David Orth (Gladstone Road Medical Centre)
- Dr Tracy Schrader (Clinic 30, Queensland AIDS Council)
- Dr Fiona Bisshop (Holdsworth House Medical Brisbane)
- Dr Cheryn Palmer (Princess Alexandra Sexual Health)
- Dr Diane Rowling (Sexual Health & HIV Service, MNHHS)
- Dr Karen Quinn (Rockhampton Sexual Health and HIV Service)
- Dr John Hooper (Kobi House, Toowoomba Health Services)
- Dr Mekala Srirajalingam (Ipswich Sexual Health Service)
- Dr Therese Ryan (Q Clinic Wide Bay Sexual Health)
- Dr Anthony Morice (Barrier Reef Medical Centre)
- Dr Arden Dearden (Earlville General Practice)
- Dr Heather McNamee (Cairns Doctors)
- Dr Elizabeth Baer (Carseldine Family Practice)
- Dr Stuart Aitken (Evandale Practice)
- Dr Adrian Castelli(Carbal Medical Services)
- Dr Paul Griffin (Mater Health Services)

- Dr Manuel Avivar-Fernandez (Newmarket 7 Day Medical Centre)

Study Locations

- Cairns Sexual Health Service
- Gladstone Road Medical Centre
- Gold Coast Sexual Health Service
- Sunshine Coast Sexual Health and HIV Service
- Townsville Sexual Health Service
- Clinic 30, Queensland AIDS Council
- Holdsworth House Medical Brisbane
- Princess Alexandra Sexual Health
- Sexual Health & HIV Service, MNHHS
- Rockhampton Sexual Health and HIV Service
- Kobi House, Toowoomba Health Services
- Ipswich Sexual Health Service
- Mt Isa Sexual Health Service
- Mackay Sexual Health and Sexual Assault Service
- Q Clinic Wide Bay Sexual Health
- Barrier Reef Medical Centre
- Earlville General Practice
- Cairns Doctors
- Carseldine Family Clinic
- Evandale Practice
- Carbal Medical Services
- Mater Health Services
- Newmarket 7 Day Medical Centre

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## Section 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. One of the ways to reduce the risk of becoming HIV positive is the use of antiretroviral medicines. These medicines are used in treating HIV positive people and when used by HIV negative people, to reduce their risk of becoming HIV positive, are known as pre-exposure prophylaxis, or PrEP for short.

This research project aims to investigate how PrEP can be provided for HIV negative people through general practitioners and sexual health clinics in Queensland and whether HIV negative people will find PrEP and the way it is delivered through this project acceptable.

This Participant Information and 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. Truvada has been recently approved by the FDA in the United States for PrEP in people who are HIV-negative, and it was approved in Australia by the Therapeutic Goods Administration for use as PrEP in May 2016. It has not yet been approved for listing on the Pharmaceutical Benefits Scheme.

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 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 tenofovir and emtricitabine 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 other 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 Queensland community. The QPrEP demonstration project will address this need.

This research has been initiated by the study doctor, A/Prof Darren Russell, and had been initially funded by Queensland Health through the Queensland HIV Foundation. Gilead Sciences, the manufacturer of Truvada (tenofovir and emtricitabine, had supported the study by providing the study drug for 50 participants for 12 months. The expanded project for up to 2,000 places announced by the Health Minister in early 2016, will use a generic study medication with the bioequivalence of Truvada (tenofovir and emtricitabine. This expanded project is known as QPrEPd.

As of Friday 17 November 2017, the original target group of 2000 participants has been achieved. This target group of 2000 participants will continue to receive PrEP as per original study protocol until 30 June 2020, when the study comes to an end.

**Effective Saturday 18 of November 2017, a further expansion to 1000 additional participants will commence recruitment (QPrEPd-X). Study participants who are recruited from 18 November 2017 will receive PrEP as per current project protocol and will continue to receive at least three (3) months of PrEP until:**

- **PrEP becomes available on the Pharmaceutical Benefits Scheme (PBS)**
- **The cost of PrEP falls significantly; or**
- **The study comes to a formal conclusion currently scheduled for 30 June 2020**

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

You will be participating in a demonstration study examining the feasibility of PrEP provision through sexual health clinics and general practice service providers.

Effective Saturday 18 of November 2017, a further expansion to 1000 additional participants will commence recruitment (QPrEPd-X). Study participants who are recruited from this date will receive PrEP as per current project protocol and will continue to receive at least three (3) months of PrEP until:

- PrEP becomes available on the Pharmaceutical Benefits Scheme (PBS)
- The cost of PrEP falls significantly; or
- The study comes to a formal conclusion currently scheduled for 30 June 2020

There are two parts to this study that you can volunteer to join.

**Part 1 – PrEP Provision** - If assessed as eligible you will be offered the opportunity to volunteer to enroll into the Part 1 – PrEP Provision arm where you will be provided with PrEP for the duration of your enrollment. You will be asked to complete routine anonymous surveys and attend your clinic at regular intervals.

**Part 2 – Monitoring and Evaluation (M&E)** Interviews - You will also be offered the opportunity to volunteer to join the Part 2 – M&E Interview arm which is designed to explore expectations and lived experiences of PrEP use and the factors influencing access, uptake and adherence.

You may choose to:

a) Participate in Part 1 only (study drug provision and surveys)
b) Participate in Part 2 only (interview)
c) Participate in Part 1 and Part 2 (study drug provision, surveys & interviews)

## Part 1 – PrEP Provision

### *Part 1 Screening and enrolment*

If you decide to participate in Part 1 of this study and have signed the consent form, your study clinician will complete a study entry questionnaire and perform various clinical assessments. Your information will be screened to make sure you are eligible for the study, such as having risk factors for HIV transmission and no evidence of hepatitis B virus infection. You will also be asked to provide an email address. This email address will be used to automatically send you a link to the online surveys. The study investigators will not have access to the email. If you don't have an email address or choose not to reveal it you will be provided with paper based survey forms.

If the results of the screening do not meet the inclusion criteria for the study, you will not be eligible to further participate in this study. If you do meet the inclusion criteria and wish to further participate in the study you will be asked to complete a short study entry survey either via a web link received through your email or a paper based version provided by your study clinician. This survey will ask you about your age, sexual identity, where you were born and education. It will also ask you about HIV and STI testing and your beliefs about PrEP.

### *Part 1 PrEP*

Consenting to PrEP requires taking a tablet of the study drug, orally, once a day. The tablet contains 200mg of emtricitabine and 300mg of tenofovir. Once you have enrolled in the study you will receive a one month supply of the study drug and receive education /advice on how best to manage your medication. At each study follow-up visit you will receive further study drug (up to 3 months' supply).

### *Part 1 Follow-up*

You will be required to visit your study clinician at one and three months after enrolment then every three months for the duration of the study. Information will be collected from you and your study clinician at these regular study visits whilst taking PrEP. At each of these clinic visits your study clinician will ask about your health and your use of the study drug. You will also have an HIV antibody test and tests for STIs at each visit and a kidney function test at the three month visit then every six months. During this time you will continue to be treated as usual by your treating doctor and he/she will make any decisions regarding your treatment that are required.

At the study entry, three month visit, and 12 monthly (or final) study visits you will be asked to complete a short survey. We will ask about your experience taking PrEP and in the 12 monthly survey we will ask questions about your

experience in the study.

These on-line surveys can be completed at the time of the visit if the clinic has suitable facilities, or via an on-line web link at a time/place of the your choosing. If you have provided an email address will receive an automated message with the survey link. If you have not provided an email address will be given a paper version of the survey and a reply paid envelope. Each survey will contain your participant unique code to allow linkage between your survey and clinical data. In the event of the on-line system not being available, you will be provided with paper based surveys with reply paid envelopes.

None of your survey answers will be shared with your study clinician because the study researchers are using the answers from these surveys to examine how PrEP influences peoples' lives at a population level over time, not at an individual level. There will also be an exit survey (If at some point you chose to withdraw/leave or when the QPrEPd study ends) asking questions about your experience of participating in the study.

During the study period you may elect to stop taking the study drug. Your study clinician will discuss with you how to plan to stop the study drug during the study period at this time.

### *Part 1 Additional costs & reimbursement*

You will not be paid for participating in Part 1 – PrEP provision arm of this project. You will be provided with the study drug free of charge during the course of the project. There is no additional cost to you for the monitoring visit tests. Your general practitioner may charge you their usual consultation fee.

### *Part 1 What do I have to do?*

Participation in Part 1 of this study does not require any restrictions to your diet or your activities. It is not anticipated that participation will affect any other medications you may be taking, however, it is important let the study clinician know any other medications you are taking. Consenting to PrEP requires taking the study drug 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.

***If you choose to participate in Part 1 of the QPrEPd study:***

- You will be expected to take the study drug 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

- You will be asked to complete short surveys at the study entry, three month visit, and 12 monthly (or final) study visits.

### Part 2 – Monitoring and Evaluation Interviews

Monitoring and evaluation of the QPrEPd demonstration project will be undertaken by the University of Queensland (UQ), School of Public Health, using a combination of information collected during Part 1 and Part 2 across the project lifetime.

Firstly de-identified data collected from the Part 1 Participant Surveys described above which will be collected at Entry, at 3 months and then 12 monthly time points until the study end point or if you should choose to withdraw. This data will be analysed to examine how expectations and attitudes towards PrEP change over time and how PrEP influences peoples' lives at a population level, not at an individual level.

Secondly you can volunteer to participate in an in-depth interview which will be conducted with a small sample of up to 40 Part 1 participants at 2 time points during the study (on enrolment and at 1 to 2 years after commencing in the study or on your withdrawal). Not everyone who volunteers will be interviewed.

The aim is to interview participants from diverse social and geographical backgrounds to reflect the geographical, social and cultural diversity of the Queensland. The UQ M&E team will use information provided in the participant entry surveys to ensure they select people from a diverse range of backgrounds and locations to offer the opportunity to join the interview phase.

These interviews will explore expectations and experiences of PrEP use and the broader social, structural, and geographical factors influencing access, uptake and adherence. By talking to you at two time points we can see if expectations of PrEP and real-life experiences of using PrEP have changed overtime.

Information from these interviews will provide information from the context of Queenslanders experiencing the roll out of PrEP that will be invaluable to the future health service and policy planning to support the ongoing access to PrEP for Queenslanders.

The information collection during the interviews is de-identified and will not be linked to your clinical information in any way. Nor will the interview data be linked at an individual level to the information collected from the study surveys you complete at entry, 3 months or each 12 month of your participation and /or exit time points.

Even if you choose not to receive PrEP, you may participate in the M&E interviews. You will be interviewed twice by the UQ M & E Team, once within 3 months of consenting and again 1 year later. The aim of these interview is to gather information about real-life experiences of people who choose not to use PrEP and explore whether these change over time. The information collected is anonymous.

### *Part 2 Screening and enrolment*

You will be asked to indicate your interest in volunteering to be interviewed for Part 2 of the study and willingness to be contacted via your preferred contact details by one of the UQ M&E team at the same time you provide informed consent to participate in Part 1 PrEP provision arm. If interested, you will be asked to provide written informed consent for Part 2 interview arm at the same time you sign your informed consent form to volunteer to participate in Part 1.

Participation in the interviews is voluntary and there is no obligation to participate should you only wish to volunteer to enrol in Part 1. If you are not interested and/or do not volunteer to be interviewed there will be no impact on your participation in Part 1 or access to PrEP. Also you can also withdraw your consent to participate in the Part 2 interviews at any time during the study without affecting your Part 1 enrolment and access to PrEP.

If you choose not to join the Part 1 PrEP provision arm of this study, you can still volunteer to join the Part 2 interview arm as this will provide us with valuable information about real-life experiences of people who choose not to use PrEP and how these may change overtime.

### *Part 2 Follow up*

If you are one of the selected participants, you will be contacted by a member of the UQ M&E team by your preferred contact details within one to three months of providing your informed consent to discuss what is involved with the interviews.

You are still free to withdraw your original expression of interest to participate in the Part 2 interviews at any time during the follow up period or when contacted by the M&E Team.

If you provide verbal informed consent during this first point of contact, the initial interview can take place at time or at a later time convenient to you & the UQ M&E researcher. At the completion of Interview 1 you will also be asked to confirm how you prefer to be contacted for the second.

### *Part 2 Additional costs & reimbursement*

You will receive a $50.00 Gift Card or Visa card in appreciation for your time for

each interview. There is no additional cost to you for participating in the Part 2 interviews.

### *Part 2 What do I have to do?*

For those participating in Part 1 and 2

Each interview will take approximately 1 hour and will be carried out by one of the UQ M&E researchers in a location of our choice. You will be asked some questions that will help us understand expectations and experiences of PrEP use and the broader social, structural, and geographical factors influencing access, uptake and adherence. By talking to you at two time points we can see if expectations of PrEP and real-life experiences of using PrEP have changed over time.

For those participating in Part 2 only

Each interview will take approximately 1 hour and will be carried out by one of the UQ M&E researchers in a location of our choice. You will be asked some questions that will help us understand the experiences of non-PrEP use and influencing factors.

For ALL interviews conducted

There are no correct answers to the questions we will ask and you are free to answer or not. If you agree to participate we will record the discussion using a digital recorder so that we can capture all the valuable information you provide. The information recorded during the interviews will be de-identified when transcribed and will not be linked to your clinical information in any way.

## 4. Other relevant information about the research project

A maximum of 3000 people who are HIV-negative and have risk factors for acquiring HIV will participate in Part 1 of this project. There are twenty three sites involved in the project:

- Cairns Sexual Health Service,
- Gladstone Road Medical Centre,
- Gold Coast Sexual Health Service,
- Sunshine Coast Sexual Health and HIV Service,
- Townsville Sexual Health Service,
- Princess Alexandra Sexual Health,
- Sexual Health and HIV Service MNHHS,
- Holdsworth House Brisbane,
- Clinic 30 Queensland AIDS Council,

- Rockhampton Sexual Health and HIV Service
- Kobi House, Toowoomba Health Services
- Ipswich Sexual Health Service
- Mt Isa Sexual Health Service
- Mackay Sexual Health and Sexual Assault Service
- Q Clinic Wide Bay Sexual Health
- Barrier Reef Medical Centre
- Earlville General Practice
- Cairns Doctors
- Carseldine Family Clinic
- Evandale Practice
- Carbal Medical Services
- Mater Health Services
- Newmarket 7 Day Medical Centre

The chief investigator for this project is A/Prof Darren Russell. The QPrEP Study Management Team is responsible for the day-to-day management and coordination of the study. Members of this team include the chief investigator and staff from the Cairns Sexual Health Service.

The QPrEPd Monitoring and Evaluation team from the University of Queensland will work closely with the chief investigator for this project is A/Prof Darren Russell and the QPrEPd Study Management Team throughout the study period.

## 5. Do I have to take part in this research project?

Participation in any part of this 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 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 or your relationship with your doctor.

## 6. 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 clinician 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.

Tenofovir and Emtricitabine 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.

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

Participation in Part 2 of this research may have no direct benefit for the individual participant, however, the information collected during Part 2 will inform the actions needed to enhance support and the ongoing delivery of the QPrEPd Demonstration Project. The M&E component of the study will also provide invaluable empirical understanding of the lived experiences and expectations of people taking PrEP and their service providers and of those who choose not to take PrEP. This data will guide the development of adequate and appropriate education, interventions and services while also providing useful data to inform public health response and future health policy.

## 8. What are the possible risks & 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 clinician. Your study clinician 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 clinician immediately about any new or unusual symptoms that you experience.

Many side effects go away shortly after PrEP is initiated. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study clinician may need to stop your PrEP. Your study clinician 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 PrEP (Tenofovir and Emtricitabine) 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 mineral density, 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 PrEP (Tenofovir and Emtricitabine). In studies of PrEP those study participants who were receiving the active study drug Tenofovir and Emtricitabine versus those who were receiving placebo were significantly more likely 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 study clinician will be performing blood tests at the beginning of the study to check you kidneys before you start and while you are taking the study drug. Your study clinician may tell you to stop taking the study drug if you develop kidney problems during the study.

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

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.

Risk to participants associated with volunteering to participate in Part 2 Monitoring and Evaluation has been determined as minimal and balanced by the value of the benefits to the participants and target community of the final research findings.

## 9. What will happen to my test samples?

The routine blood tests include a test for HIV and hepatitis B virus (HBV). This is because the study clinicians 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 clinicians 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.

## 10. 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 clinician 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 clinician 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 clinician 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.

## 11. 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 to let the study clinician 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 clinician about any changes to these during your participation in the research project. Your study clinician will explain to you which treatments or medications need to be stopped for the time you are involved in the QPrEP study.

## 12. 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 clinician 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 will be asked to complete a short final visit survey, however you may choose not to do this. If you have volunteered for the monitoring and evaluation (M&E) phase of the project, you will also be offered the opportunity to complete the second interview. However, you may choose not to do this.

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 QPrEP-X study.

## 13. 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.

### 14. What happens when the research project ends?

Up to 1000 new study participants, who are recruited from 18 November 2017 will receive PrEP as per current project protocol and will continue to receive at least three (3) months of PrEP until:

- PrEP becomes available on the Pharmaceutical Benefits Scheme (PBS)
- The cost of PrEP falls significantly; or
- The study comes to a formal conclusion currently scheduled for 30 June 2020

At the end of the study 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 study clinician.

## Section 2 How is the research project being conducted?

### 15. What will happen to information about me?

By signing the consent form you consent to the study clinician 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 and will disclosed only with your permission, or except as required by law.

The information your study clinician collects about you, including results of relevant laboratory tests (such as HIV antibody, sexually transmitted diseases tests) will be entered onto a study form for the researchers. This form will include your month and year of birth and a unique number assigned to you. Only information relevant to the study will be collected on these forms. Information about your participation in this research project may be recorded in your health records.

The survey forms you will be asked to complete will include your month and year of birth and a unique number assigned to you.

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.

### 16. 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.

## 17. Who is organising and funding the research?

This research project is being conducted by the Chief Investigator, A/Prof Darren Russell and is being funded by Queensland Health. The manufacturer of Truvada, Gilead Sciences, supported the initial project by providing the study drug for the first 50 places in the original QPrEP project. The State Government has provided funding for the project expansion to "QPrEPd" at 2000 participants in November 2016 and a further 1000 participants from November 2017, for a total of up to 3000 places using a generic drug formulation.

No member of the research team will receive personal financial benefit from your involvement in this research project (other than their ordinary wages).

## 18. 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 a Queensland HREC. 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.

## 19. 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 any of the following people:

Cairns Sexual Health Service
A/Prof Darren Russell (07 4226 4769)

Gladstone Road Medical Centre
Dr David Orth (07 3844 9599)

Gold Coast Sexual Health Service
Dr Maree O'Sullivan (07 5687 9200)

Sunshine Coast Sexual Health and HIV Service
Dr Kuong Taing (07 5470 5244)

Townsville Sexual Health Service
Dr Arun Menon (07 4433 9600)

Princess Alexandra Sexual Health
Dr Cheryn Palmer (07 3176 5881)

Sexual Health and HIV Service, MNHHS
Dr Diane Rowling (07 3837 5611)

Holdsworth House Medical Brisbane
Dr Fiona Bisshop (07 3894 0794)

Clinic 30, Queensland AIDS Council
Craig Atkinson (07 3017 1777)

Rockhampton Sexual Health and HIV Service
Dr Karen Quinn (07 4932 5440)
Kobi House, Toowoomba Health Services
Dr John Hooper (07 4616 6446)

Ipswich Sexual Health Service
Dr Mekala Srirajalingam (07 3817 2428)

Mt Isa Sexual Health Service
Dr Arun Menon (07 4764 0200)

Mackay Sexual Health and Sexual Assault Service
Dr Arun Menon (07 4968 3919)

Q Clinic Wide Bay Sexual Health
Fiona Stack (07 4150 2754)

Barrier Reef Medical Centre
Dr Anthony Morice (07 4051 6299

Earlville General Practice
Dr Arden Dearden (07 4054 3488)

Cairns Doctors
Dr Heather McNamee (07 4041 7099)

Carseldine Family Clinic
Dr Elizabeth Baer (07 3263 4500)

Evandale Practice

Dr Stuart Aitken (07 5510 3122)

Carbal Medical Services
Dr Adrian Castelli (07 4639 7300)

Mater Health Services
Dr Paul Griffin (07 3163 7302)

Newmarket 7 Day Medical Centre
Dr Manuel Avivar-Fernandez (07 3356 3300)

If you want any further information concerning the Monitoring and Evaluation of this project or, you can contact any of the following people at The University of Queensland School of Public Health (288 Herston Rd, HERSTON Qld 4006):

Dr Judith Dean (07 3346 4876) Email: j.dean4@uq.edu.au
Dr Lisa Fitzgerald (07 3346 5244) Email: l.fitzgerald@sph.uq.edu.au
Dr Owain Williams (07 3346 4874) Email: o.williams@uq.edu.au

If you have any complaints about any aspect of the study, the way it is being conducted or any questions about being a research participant in general, please contact the Reviewing HREC approving this research and HREC Executive Officer.

Reviewing HREC name: Gold Coast Health Service District Human Research Ethics Committee
HREC Officer: Vanessa Druett
Telephone: (07) 5687 3879
Email: GCHEthics@health.qld.gov.au

**Consent Form – QprEPd-X REDCap Study ID:_____**

| | |
|---|---|
| Title | The Queensland Pre-Exposure Prophylaxis Demonstration Project Expansion |
| Short Title | The QPrEP Study (QPrEPd-X) |
| Protocol Version | 3.6 dated13 October 2017 |
| Project Sponsor | Cairns and Hinterland Hospital and Health Service |
| Chief Investigator | A/Prof Darren Russell |
| Location | Cairns Sexual Health Service, , Gladstone Road Medical Centre, Sunshine Coast Sexual Health and HIV Service, Gold Coast Sexual Health Service, Townsville Sexual Health Service, Sexual Health and HIV Service MNHHS, Princess Alexandra Sexual Health Clinic,Clinic 30 Queensland AIDS Council, Holdsworth House Medical Brisbane, Rockhampton Sexual Health and HIV Service, Kobi House Toowoomba Health Services, Mt Isa Sexual Health Service, Mackay Sexual Health and Sexual Assault Service, Q Clinc Wide Bay Sexual Health, Barrier Reef Medical Centre, Earlville General Practice, Cairns Doctors, Carseldine Family Clinic, Evandale Practice, Mater Health Services, Carbal Medical Services, Newmarket 7 Day Medical Centre |

### *Part 1 – PrEP Provision Declaration by Participant*

Up to 1000 new study participants who are recruited from 18 November 2017 will receive PrEP as per current project protocol and will continue to receive at least three (3) months of PrEP until:

- *PrEP becomes available on the Pharmaceutical Benefits Scheme (PBS)*
- *The cost of PrEP falls significantly; or*
- *The study comes to a formal conclusion currently scheduled for 30 June 2020*

1. I have carefully read and understand the information presented in the Participant Information Sheet
2. I understand the purposes, procedures and risks of the research described in the project.
3. I give permission for my study clinician to release information to the study researchers and I understand that such information will remain confidential.
4. I have had an opportunity to ask questions and I am satisfied with the answers I have received.
5. 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.
6. 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 Clinician**

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

Name of Study Clinician (please print)_____

Signature_____Date_____

_____

*Part 2 – Monitoring and Evaluation Interviews*

**REDCap Study ID:_____**

**Declaration by Participant**

- I have carefully read and understand the information presented in the Participant Information Sheet about the Part 2 M&E Interviews
- I understand the purposes, procedures and risks of the research described in the project.
- I give permission for my study clinician to release information to the study researchers and 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.

1. I am interesting in participating in the Part 2 Monitoring and Evaluation Interviews

   Yes ☐ No ☐

2. I consent to be contacted by a member of the University of Queensland School of Public Health Monitoring and evaluation

   Yes ☐ No ☐

Name of Participant (please print)_____

Signature_____Date_____

**Declaration by Study Clinician**

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

Name of Study Clinician (please print)_____

Signature_____Date_____

## Contact Details for the Part 2 M&E Interviews

**REDCap Study ID:_____**

I consent to be contact by the UQ M&E team by the following means (Please provide details)

1. Phone _____ Yes ☐ No ☐

2. Email: _____@_____Yes ☐ No ☐

Please note this information will be stored separately in a locked and secured location on the University of Queensland grounds and will only be used for the purposes of contacting you to arrange a suitable time and place for the interview to occur

Name of Participant (please print)_____

Signature_____Date_____

**Declaration by Study Clinician**

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

Name of Study Clinician (please print)_____

Signature_____Date_____

# Revocation of Consent Form – QPrEPd-X Study

| **REDCap Study ID:_____**Title | The Queensland Pre-Exposure Prophylaxis Demonstration Project |
|---|---|
| Short Title | The QPrEP Study (QPrEPd-X) |
| Protocol Version | 3.6 dated 13 October 2017 |
| Project Sponsor | Cairns and Hinterland Hospital and Health Service |
| Chief Investigator | A/Prof Darren Russell |
| Location | Cairns Sexual Health Service, , Gladstone Road Medical Centre, Sunshine Coast Sexual Health and HIV Service, Gold Coast Sexual Health Service, Townsville Sexual Health Service, Sexual Health and HIV Service MNHHS, Princess Alexandra Sexual Health Clinic,Clinic 30 Queensland AIDS Council, Holdsworth House Medical Brisbane, Rockhampton Sexual Health and HIV Service, Kobi House Toowoomba Health Services, Mt Isa Sexual Health Service, Mackay Sexual Health and Sexual Assault Service, Q Clinic Wide Bay Sexual Health, Barrier Reef Medical Centre, Earlville General Practice, Cairns Doctors, Carseldine Family Clinic, Evandale Practice, , Mater Health Services, Carbal Medical Services, Newmarket 7 Day Medical Centre |

I hereby wish to WITHDRAW my consent to participate in this study. I understand that withdrawal will not jeopardise my relationship with my study clinician nor affect my future health care.

Name of Participant (please print)_____

Signature_____Date_____

This section for Revocation of Consent should be forwarded to:

A/Prof Darren Russell
Chief Investigator
Cairns Sexual Health Service
PO Box 902
Cairns 4870

Email: Darren.russell@health.qld.gov.au
Fax: 07 4226 4771