Appendix I Pre-screening Participant Information Sheet and Informed Consent Form Template

Site: Insert Header with institution's name or institution's letterhead as required

Participant Information Sheet/Consent Form PRELUDE Study Pre-screening

[Insert site name if required]

Title	Pre-screening for implementation of HIV preexposure prophylaxis with antiretroviral medications among people at high risk for HIV infection: A demonstration project
Short Title	The PRELUDE Study pre-screening
Protocol Version	15 August 2014
Protocol Number	HEPP 1403
Project Sponsor	The Kirby Institute for Infection and Immunity in Society
Coordinating Principal Investigator	Dr. Iryna Zablotska, The Kirby Institute
Associate Investigator(s)	*[Site: insert if required by institution]*

Part 1: What does my participation involve?

1 Introduction

You are invited to provide pre-screening information to see if you may qualify for a research project called the PRELUDE Study. You are invited because you say you are HIV-negative and may be at increased risk of getting HIV (Human Immunodeficiency Virus). HIV is the virus that causes Acquired Immunodeficiency Syndrome, or AIDS. In the PRELUDE research project, a medicine that has been used to treat people who *have* HIV will be given to HIV-negative people to evaluate its use as the means to *lower* their chance of getting HIV. This is called preexposure prophylaxis or 'PrEP.' Prophylaxis means doing something to prevent an illness or infection.

This Participant Information Sheet/Consent Form (PICF) tells you about the pre-screening process for the PRELUDE Study. Knowing what is involved will help you decide if you want to pre-screen for the study. There is a separate Participant Information Sheet/Consent Form for the PRELUDE Study, which explains all of the procedures, risks, and benefits associated with PrEP and the PRELUDE Study 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 friend, partner, family member or your doctor.

Participation in this pre-screening is voluntary. If you don't wish to take part, you don't have to. You will receive the same quality of care whether or not you take part.

If you decide you want to pre-screen for the PRELUDE research project, you will be asked to sign the consent section of this document. By signing it you will be telling us that you:

- Understand what you have read
- Consent to answer the pre-screening questions for the PRELUDE Study
- Consent to complete an on-line survey about attitudes, behavioural and lifestyle as 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 pre-screening process?

The PRELUDE Study will evaluate a new additional way to lower people's chances of getting HIV and will enrol participants who meet certain criteria. The purpose of the pre-screening for the PRELUDE Study is to see whether you meet certain criteria as related to your risk of getting HIV through sex. The purpose of completing the on-line survey questions is to collect basic information about why you want to take PrEP, your attitudes regarding PrEP and HIV, and your risk behaviours.

This research study is being conducted by a group of investigators at the Kirby Institute, the University of New South Wales, and lead by Dr. Iryna Zablotska.

3 What does participation in this pre-screening involve?

The pre-screening process may be completed before or on the same day as the PRELUDE Study screening visit.

The pre-screening consent form must be signed by you before you are asked the HIV risk questions, and before you complete the on-line attitude, behaviour and lifestyle survey.

At the clinic

For this pre-screening process, doctors who are also researchers on this study will make sure you are a good candidate for PrEP. You will be asked approximately ten questions to see if you are at increased risk of getting HIV from sex. The doctor will then give you a unique identification number, a website address and a user name, for you to use to complete an on-line survey.

In order to qualify for the pre-screening, you must:

- Be at least 18 years old
- Live in NSW, or visit NSW enough to attend follow-up visits in the PRELUDE Study.
- Be willing to take a computer-based survey about your attitudes, behaviours and lifestyle
- Be willing and able to consent to pre-screening.

After the pre-screening clinic visit

You will be asked to use your unique identification number to complete a self-administered on-line survey in a location of your choice (e.g. at home), ideally within two and no more than seven calendar days of the clinic visit. If you qualify and start to screen for the PRELUDE Study, you will have to complete the pre-screening survey before you start taking the PrEP medication.

The survey will ask questions about why you want to take PrEP, and how you feel about PrEP. It should take about 30 minutes to complete the pre-screening survey.

Additional costs and reimbursement

You will not be paid and there will be no additional costs to you to participate in this pre-screening process.

This research project has been designed to make sure the researchers interpret the results fairly and appropriately. It has also been designed to keep study doctors or participants from jumping to conclusions.

4 Other relevant information about the research project

Participants in this pre-screening process will be adults who are HIV-negative and are at risk of getting HIV through sex. It is anticipated that between 300 and 600 people will complete this pre-screening process.

5 Do I have to take part in this pre-screening process?

Participation in any research project, including this pre-screening process, is voluntary. You do not have to be in this project if you do not want to. If you decide to pre-screen now, it is your right to change your mind later. You are free to withdraw from the pre-screening at any time. If you do decide to pre-screen, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

If you complete the screening process but either do not qualify for the study or decide not to start taking PrEP, you will be asked to complete an optional behavioural and lifestyle survey including questions about why you did not qualify/did not decide to start taking PrEP, so that we better understand how the screening and enrollment process works.

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 [insert Institution].

6 What are the alternatives to participation?

You do not have to be in the pre-screening process or the PRELUDE Study to receive treatment at this clinic. A separate PRELUDE Study information sheet and consent form reviews other alternatives and options to prevent HIV.

7 What are the possible benefits of taking part?

There is no guarantee or promise that you will receive any benefits from pre- screening for the PRELUDE Study. There is also no guarantee or promise that you will be enrolled in the PRELUDE study and receive PREP. However, people may like the idea that they are contributing to new knowledge about the prevention of HIV, and how people feel about PrEP and why they want to take PrEP.

8 What are the possible risks and disadvantages of taking part?

The questions we will ask you about your sexual behaviour may make you feel uneasy. However, you can stop answering the questions at any time and can change your mind about participating in this pre-screening at any time.

You may feel that some of the questions asked in the survey are stressful or upsetting. If you do not wish to answer a survey question, you may skip it and go to the next question, or you may stop immediately.

If you become upset or distressed as a result of your participation in the pre-screening, the research team 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 team. This counselling will be provided free of charge.

9 What if I withdraw from this pre-screening process?

If you decide not to complete the pre-screening process and have not yet completed the on-line survey, please let a member of the research team know.

If you do withdraw, you will be asked to complete and sign a 'Withdrawal of Consent' form; this will be provided to you by the research team.

If you do withdraw your consent from pre-screening, all the personal information that has already been collected for pre-screening will be kept so 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 about pre-screening, but they will not contain any personal information about you, such as your name or address. If you do not want this to happen, you must tell the researcher before you pre-screen.

Part 2 How is the pre-screening process being conducted?

10 What will happen to information about me?

How information is used and stored

By signing the consent form you consent to the research team collecting and using personal information about you for the pre-screening research project. Any information collected that can identify you will remain confidential. Your signed pre-screening consent form will be stored safety and kept confidential at the clinic.

Your de-identified answers to the HIV risk questions, along with your gender, age and sexual orientation will be shared with the researchers at the Kirby Institute. The Kirby researchers will not see your signed consent form and therefore will not know your identity.

Only the researchers at the Kirby Institute will have access to your internet-based survey information. This information will be stored in a password-protected database (SurveyGizmo), and will be treated as confidential and securely stored. All of your answers will be stored under your unique pre-screening code number, and the Kirby researchers will not know your identity. The Kirby researchers WILL be able to use your code number to link your survey answers with your HIV risk question answers. This will allow them to learn more about why people would like to take PrEP. The survey will be protected by passwords and University of New South Wales firewalls. **The researchers at the Kirby Institute will not share any of your survey answers with your clinic doctors, nurses or other staff.**

The paper based form with your HIV risk answers 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.

Any information obtained for the purpose of this pre-screening and for any future related research 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.

Publication and presentation of research findings

The findings from the pre-screening part of the PRELUDE Study will be published and/or presented in a variety of places, most likely combined with everyone else's information. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

Your rights to your information

In accordance with relevant Australian and New South Wales 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.

Information storage after the study

After the end of the study, all study files associated with the PRELUDE Study will be archived in a locked storage facility and kept for at least 15 years after the end of the study. Coded data in electronic form will also be stored for this amount of time.

11 Complaints and compensation

If you suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

If you have any complaints about any aspect of pre-screening, the way it is being conducted or any questions about being a research participant in general, then you may contact the complaints person at the end of this information sheet.

12 Who is organising and funding the research?

The PRELUDE research project and this pre-screening is being conducted by the PRELUDE study team lead by the Chief Investigator, Dr Iryna Zablotska at the Kirby Institute, and is being funded by the NSW Ministry of Health. No financial benefits are expected for anyone as a result of this pre-screening process.

13 Who has reviewed the pre-screening procedure?

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 pre-screening and of the PRELUDE Study have been approved by the HREC of the St. Vincent's Hospital, Darlinghurst NSW. 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.

14 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 about this project, you can contact the study chief investigator Dr. Iryna Zablotska on 9385-0951 or any of the following people:

Clinic contact person (for each study site to complete; may provide more than one if necessary)

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person (for each study site to complete)

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

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	St. Vincent's Hospital Sydney HREC
HREC Executive Officer	Contact person - HREC Executive Officer
Telephone	8382 2075
Email	research@stvincents.com.au

Local HREC Office contact (Single Site -Research Governance Officer – for each study site to complete)

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

Consent Form –PRELUDE Study Pre-screening

Title	Pre-screening for: implementation of HIV preexposure prophylaxis with antiretroviral medications among people at high risk for HIV infection: A demonstration project
Short Title	The PRELUDE Study pre-screening
Protocol Version	15 August 2014
Protocol Number	HEPP 1403
Project Sponsor	The Kirby Institute for Infection and Immunity in Society
Coordinating Principal Investigator	Dr. Iryna Zablotska, The Kirby Institute
Associate Investigator(s)	[insert if required by institution]

1) Declaration by Participant

I have read the PRELUDE Study pre-screening 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 pre-screening as described.

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 pre-screening process 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 _____

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.

Declaration by Study Doctor/Senior Researcher

I have given a verbal explanation of the pre-screening process, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† 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
[Note: Site specific footers may be required per instructions on page ii]

Form for Withdrawal of Participation – PRELUDE Study Pre-screening

Title	Pre-screening for implementation of HIV preexposure prophylaxis with antiretroviral medications among people at high risk for HIV infection: A demonstration project
Short Title	The PRELUDE Study pre-screening
Protocol Version	15 August 2014
Protocol Number	HEPP 1403
Project Sponsor	The Kirby Institute for Infection and Immunity in Society
Coordinating Principal Investigator	Dr. Iryna Zablotska, The Kirby Institute
Associate Investigator(s)	[insert if required by institution]

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 Study Doctor/Senior Researcher will need to provide a description of the circumstances in the participant's source documentation.

Declaration by Study Doctor/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 Study Doctor/
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.

Appendix II Participant Information Sheet and Informed Consent Form Template

Site: Insert Header with institution's name or institution's letterhead as required

Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

[Insert site name if required]

Title	Implementation of HIV preexposure prophylaxis with antiretroviral medications among people at high risk for HIV infection: A demonstration project
Short Title	The PRELUDE Study
Protocol Version	30 September 2015
Protocol Number	HEPP 1403
Project Sponsor	The Kirby Institute for Infection and Immunity in Society
Coordinating Principal Investigator	Dr. Iryna Zablotska, The Kirby Institute
Associate Investigator(s)	*[Site: insert if required by institution]*

Part 1: What does my participation involve?

1 Introduction

You are invited to take part in a research project called PRELUDE because you are HIV-negative and may be at increased risk of getting HIV (Human Immunodeficiency Virus). HIV is the virus that causes Acquired Immunodeficiency Syndrome, or AIDS. In this research project, a medicine that has been used to treat people who *have* HIV is given to HIV-negative people to evaluate its use as the means to *lower* their chance of getting HIV. This is called preexposure prophylaxis or 'PrEP.' Prophylaxis means doing something to prevent an illness or infection.

This Participant Information Sheet/Consent Form (PICF) tells you about this research project. It explains the tests, treatments and the study requirements 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 friend, partner, family member or your doctor.

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

If you decide you want to take part in the PRELUDE research project, you will be asked to sign the consent section of this document. By signing it you will be 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?

More and more people in Australia are getting HIV today, despite all prevention efforts, the availability of condoms and HIV testing. The NSW government would like to eliminate new HIV cases by the year 2020. This research will evaluate a new additional way to lower people's chances of getting HIV.

The drug being used in this project is called TRUVADA, and it is made by Gilead Sciences, Inc. TRUVADA is a single tablet made up of two different HIV medications: Viread (tenofovir disoproxil fumarate) and Emtriva (emtricitabine). Both these drugs have been widely used for many years to treat HIV. When used with other medicines in people who already ***have*** HIV, TRUVADA may help reduce the amount of HIV virus in the blood. It also may increase the number of cells in the blood that help fight off other infections. TRUVADA does not cure HIV or AIDS, and it is not an HIV vaccine.

In order for medicines to be used in Australia, they have to be approved by the Australian Federal Government. As a treatment for people who already have HIV, TRUVADA is approved for use in Australia, the United States, and other countries. As a medicine for PrEP, to lower chances of HIV in those who are not infected, TRUVADA has been approved in the US, but not in Australia. Therefore, in Australia, this study is considered experimental.

The purpose of the PRELUDE Study is to develop and evaluate a model of PrEP delivery in health services. It will see whether PrEP is an effective, safe and manageable option to help lower people's chances of getting HIV through sex. It will also study whether people in NSW find it easy and agreeable to take PrEP every day, why they take it, how it feels to take it, and whether it changes how they have sex. Finally, it will study how easy it is for doctors to use it with their patients, and what it costs the NSW government and clinics to provide PrEP.

This research study is being conducted by a group of investigators at the Kirby Institute, the University of New South Wales, and lead by Dr. Iryna Zablotska. It is funded by the NSW Ministry of Health. Gilead Sciences, who makes TRUVADA, is providing the study drug.

How well does PrEP work?

Research in other countries, including the U.S., has shown that the chances of getting HIV through sex is lowered for people who take PrEP ***and*** use condoms correctly during sex. How well PrEP works depends on how good people are at taking PrEP ***every day***.

Overall, studies in other countries have shown that taking PrEP lowers the risk of getting HIV by about 86 percent in homosexual, bisexual, and other men who have sex with men, and by about 70 percent in heterosexual adults. This means that some people on these research studies still got infected with HIV even though they were taking PrEP. However, when researchers looked specifically at people who were taking PrEP every day, they found that the risk of getting HIV was lowered even more. In one study of 2499 homosexual, bisexual and other men who have sex with men, those who took their PrEP pill every day had their risk of getting HIV lowered by 92 percent. In contrary, the risk of HIV infection was higher in people who did not take their tablets daily.

3 What does participation in this research involve?

Your involvement in the PRELUDE study will last up to about 36 months (3 years). This includes up to two weeks for screening, up to 30 months of taking PrEP (please note that the original period of up to 12 months is now extended to up to 30 months), and the completion of one follow-up visit and two

follow-up questionnaires after you stop taking PrEP. The overall study will run for about five years.

By entering the study, you are not committing to being in the study and taking PrEP for the whole 30 months. For example, your participation in the study may end if you are no longer at risk of getting HIV through sex. You can also withdraw from the study at any time for your own reasons.

Screening Visit

The consent form must be signed by you before any study assessments are done.

First, doctors who are also researchers on this study will confirm that you are a good candidate for PrEP. .
A number of tests will be conducted as a standard of care in New South Wales, Australia.

You will be tested for sexually transmitted infections, including HIV, chlamydia, gonorrhoea and syphilis. For gonorrhoea and chlamydia testing for men, this will be done by performing a swab of your rectum and collecting urine. Blood will be collected for syphilis, HIV testing and Hepatitis B testing.

For gonorrhoea and chlamydia testing for women, this will be done by performing [*sites to fill in method*: *a swab of your cervix, and a swab of your rectum if you have had anal sex in the last year AND/OR will be done by collecting urine]*. Blood will be collected for syphilis, HIV testing and Hepatitis B testing .

Your health and blood will be checked to make sure you are not at increased risk of possible side effects from TRUVADA, such as kidney or liver problems. You will also have a medical examination and will be asked about your medical history. If you are a woman who can get pregnant, you will have a pregnancy test before starting PrEP and while taking it, so that you and your doctor can together make an informed decision whether you start and continue taking PrEP.

Because both of the drugs in TRUVADA work against hepatitis B, you will be tested to know if you have active hepatitis B. This will allow doctors to recommend you an appropriate treatment. You may also be offered a vaccine against hepatitis B if the result of this test is negative. If the results show you were exposed earlier to hepatitis B and the infection has resolved, then you can be in the study. You may also be tested for Hepatitis C if this is considered standard at the clinic.

For all of these tests, [site to insert volume in millilitres and teaspoons or tablespoons, e.g. x tablespoons/y millilitres] of blood will be collected from a vein in your arm.

The samples collected for the standard of care tests will include: [site to insert accordingly.]

In order to qualify for the study, you must:

- Be at least 18 years old
- Have a negative HIV test within seven days of starting PrEP
- Not show possible signs of having HIV
- Be at high and ongoing risk for getting HIV
- Live in NSW, or visit NSW enough to attend all of your follow-up visits
- Be eligible for Medicare
- Be able to take TRUVADA once every day for at least 30 days
- Be able to attend clinic follow-up visits
- Be willing and able to have your blood collected at some of the follow-up visits as outlined below.
- Be willing to take a computer-based survey about your attitudes, behaviours and lifestyle at the beginning of the study, after each follow-up visit, and twice after you stop taking PrEP.
- Be willing and able to consent to this study.

You will not be allowed to be enrolled in this study if you have certain kidney or liver problems, if you have to take certain medications that might make PrEP unsafe, if you have known allergies to PrEP, or if you are breastfeeding. You also cannot be in this study if you have any conditions that would make it difficult for you to take PrEP every day, such as certain mental health issues, memory loss, difficulty thinking or some intellectual disabilities. If you will be in prison or if you plan to be away from NSW for a period of 3 months or longer during the study, you cannot be in this study because you will not be able to attend your follow-up visits.

In addition, the study doctor may ask you whether you have any symptoms consistent with a new HIV infection and you have experienced any known or suspected exposure to HIV during the last 30 days. If you have, you will receive additional HIV testing, and may be asked to delay starting PrEP for up to one month until the conclusive result of that testing. **It is very important for your safety during this study that you tell the doctor if you are experiencing any of the following at screening or before you start PrEP. It is also very important that you tell your doctor about any of these at your follow-up visits. If you do but it is not time for your regularly-scheduled follow-up visit, please contact your doctor or the study coordinator.**

- Fever
- Feeling tired (fatigue)
- Muscle aches (myalgia)
- Joint aches (arthralgia)
- Skin rash
- Headache
- Sore throat (pharyngitis)
- Night sweats
- Swelling of the lymph nodes around the head and neck (cervical adenopathy)

There may be a few days between the time you start screening for this study, and the time you can start taking PrEP medication. If you encounter a high-risk sexual event before you start taking TRUVADA, please tell your study doctor immediately, so that your study doctor can assess whether you need to receive medication for "Post-Exposure Prophylaxis," or PEP before you start taking PrEP. This will not affect your ability to start taking PrEP once you finish with PEP if you are eligible.

When you first asked about this research, the clinic doctor collected some basic information about who is interested in PrEP and why (age, gender, sexual orientation, and answers to the HIV risk questions). You also completed an internet based survey on attitudes, behaviour and lifestyle. The pre-screening questionnaire did not contain any identifiable information. If you decide to be in this study, you will be asked to consent to allow that information to be linked with your PRELUDE study information. The study will also collect information about any PEP you may have taken right before starting PrEP.

Starting PrEP

After you have met all study criteria, you will be given a prescription for 30 days of TRUVADA. You will be asked to start taking TRUVADA as PrEP immediately. Your doctor will provide you with information to help you remember to take TRUVADA every day. You will also receive condoms, and counselling on condom use and safe sex.

It is important to know that:

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

How do I take PrEP?

A tablet of TRUVADA must be taken by mouth once a day, at about the same time every day, and it is recommended to be taken with food. For this study, you will be asked to take PrEP daily for at least 30 days. You may continue to take PrEP every day for up to 30 months total (please note that the original period on PrEP up to 12 months is now extended to up to 30 months).

If you miss a dose of TRUVADA, your doctor may advise you to take the missed pill as soon as you remember on that same day, but to not take more than one dose of TRUVADA in a 24 hour period. Your doctor may also advise that if you miss a dose, and it is almost time for your next dose, to wait and take the next dose at your regular time. Contact your medical provider as soon as possible if you take more than one pill of TRUVADA a day, to avoid overdosing.

TRUVADA should be stored at room temperature in its original container. The container should be kept tightly closed and out of the reach of children. Do not give TRUVADA prescribed to you to other people.

Follow-up Visits while taking PrEP

After you start the study, you will attend a follow-up visit at the clinic one month after you start taking PrEP, and then every three months after you start taking PrEP, for up to 30 months (that is the original period of taking PrEP up to 12 months is now extended to up to 30 months). At each of these visits, you will have an HIV test. It is very important that you take these HIV tests because TRUVADA cannot be taken alone by people who are HIV-positive (see HIV Infection section below).

At each follow-up visit you will be asked about your health, how well you remembered to take TRUVADA, and your sexual practices including safer sex practices. Each study visit will be about 15 minutes longer than your regular clinic visits.

At each of the quarterly visits (every three months), you will again be tested for HIV and sexually transmitted infections, and will be tested for your kidney and liver health. A total of about [site to insert volume in millilitres and teaspoons or tablespoons, e.g. x tablespoons/y millilitres] of blood will be collected from a vein in your arm for these tests. If you are a woman who can get pregnant, you will also be given a pregnancy test. You will be reminded about how to take PrEP, and will be given safe sex information, services, or referral for any services you might need.

You may also have an additional 25 millilitres (ml) or 1 and a half tablespoons of blood collected at some of the follow-up visits,, to measure the amount of TRUVADA that is present in your blood. You will have no more than three collections of this blood during the study.
If you are still eligible to continue taking PrEP, you will be given a new prescription for TRUVADA at these visits.

All of these follow-up procedures and discussions are considered standard care for people who are at risk for HIV infection and/or are taking anti-HIV medications. This means that even if PrEP wasn't considered research, these things would be done for your health and safety.

Within two and no more than within seven days of each clinic visit while you are taking PrEP, you will complete a self-administered, web-based, online questionnaire. The questionnaire will take approximately 30 minutes to complete. If you do not have a home computer that you are able to use, then you will be provided an alternate means of completing the questionnaire. The survey does not work well on mobile devices, so should be completed on a desktop or laptop computer. The questions will ask about things like your relationships, sexual practices and other related behaviour (in the preceding three months or since your last online questionnaire), your beliefs and attitudes about HIV and its prevention, and your experience with taking PrEP. It will also ask about how often you have taken your study medications since your previous online questionnaire. This includes information on when you have taken or missed doses of PrEP and when you have had and had not use condoms. The more accurate the information, the more useful it will be for the research and future use of PrEP.

The answers to the online questionnaire go directly to the researchers at the Kirby Institute. They will not share any of your survey answers with your clinic, doctors, nurses or other staff. The study

researchers are using the answers from these surveys to see how PrEP changes peoples' lives in general, not at an individual level.

Stopping PrEP

It is your right as a research participant to decide to stop taking PrEP at any time. During the 30-month period, you may choose to stop the PrEP medication if you feel that you no longer need it. Your study doctor may also have you stop the PrEP medication if she or he feels it is not needed, or it is not safe for you stay on PrEP. For example, you will be stopped from the study if you become HIV positive, if you start to experience kidney, liver or other unacceptable health problems, or if you need medication that interacts with TRUVADA.

It is strongly recommended for your safety that you take PrEP for at least 30 days at a time. Your doctor will discuss with you how to plan to stop PrEP during the study period if you need to. This may also involve taking TRUVADA as "Post-Exposure Prophylaxis," or PEP, if you and your doctor find out that you might have been exposed to HIV. If at any time during the study you stop taking PrEP and start taking PEP, the results of your HIV, STI and other tests taken because you are on PEP will be collected for the study as well. If you become HIV positive during this study, the results of any additional tests about your HIV infection, such as tests of resistance to different HIV treatments, will be collected for this study.

When you stop taking PrEP at any time during the study (including at 30 months), you will attend an end-of-study visit. At this visit, all quarterly follow-up visit procedures will be conducted.

If you change your mind about stopping TRUVADA and want to start taking it again, you can re-enter the study within the six months after you stopped, as long as you still qualify and the study is still open for re-enrolment. The option to re-enter will not be available during the last four months of the study or if the study has been filled.

Follow-up Visits after you stop taking PrEP

Three and six months after you stop taking PrEP, you will complete the on-line questionnaires for the researchers at Kirby, as already described. You will also be asked if the researchers can have access to your information from the NSW HIV Registry up to six months after you stop taking PrEP. That will allow the researchers to see if you test positive for HIV after you stop taking PrEP.

Additional costs and reimbursement

You will not be paid and there will be no additional costs to you to be in this project. All tests and medical care required as part of the research project will be provided to you as it normally would be through Medicare. During the 30 month period, the medication will be provided free-of-charge by Gilead Sciences. Because this study wants to know what it will be like to use PrEP in the real-world, you will not be reimbursed for your travel to the clinics, clinic parking, your time, or other expenses associated with the research project.

This research project has been designed to make sure the researchers interpret the results fairly and appropriately. It has also been designed to keep study doctors or participants from jumping to conclusions.

4 What do I have to do?

Participation in this study does not require any changes to your diet or to your participation in sports. It is important let the study doctor know any other medications you are already taking or start taking while on TRUVADA.

Even if this was not a research study, all people who take PrEP will need to do other things to prevent getting infected with HIV and other sexually transmitted infections.

People who take PrEP must:

- **Take PrEP every day**. Not taking PrEP every day can increase your risk of getting HIV. Because this is so important, your doctor will talk with you about the best ways to help you remember to take your pill.
- **Continue using condoms every time when having sex:** PrEP is not 100 percent effective in preventing HIV, and does not protect against getting other sexually transmitted infections, like herpes, gonorrhoea, and syphilis.
- **Let the study doctor know if they have not been taking PrEP every day and may have been exposed to HIV:** When taken every day, PrEP can still take at least seven days to build up the maximum protection. If you think you have been exposed to HIV, your doctor will discuss your risk with you, and whether you may need Post-Exposure Prophylaxis. Do not wait until your next follow-up visit to discuss this with your doctor. It is important to start Post-Exposure Prophylaxis within 72 hours after you were exposed to HIV.

It is also important to know that:

- Taking extra pills will not provide you with extra protection.
- PrEP is not a "morning after" pill; it will not work if only taken right before or right after exposure to HIV.
- If you decide to stop taking PrEP for any reason, you should make sure you have taken PrEP every day for four weeks after the last time you may have had sex that put you at risk of HIV.
- If you have been exposed to HIV, your doctor may recommend to stop PrEP and take a course of Post-Exposure Prophylaxis.

5 Other relevant information about the research project

Participants in this study will be adults who are HIV-negative and are at risk of getting HIV through sex. The study allows "up to 300 person-years" of PrEP. This means that if everyone who participates takes one year of TRUVADA, there will be 300 people in the study. However, there may be more people in the study if at least some participants take TRUVADA for less than one year.

Everyone in the study will take TRUVADA for PrEP, and everyone will have the same study visits. The PRELUDE Study is open to all adults regardless of sex, gender or sexual preference. There will be between four and 12 sites involved in the project. The coordinating principal investigator for this project is Dr Iryna Zablotska. The PRELUDE Study Management Team is responsible for the day-to-day management and coordination of the study. Each clinic in the study also has investigators who are part of the study.

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

Participation in any research project is voluntary. You do not have to be in this project if you do not want to. If you decide to be in this project now, it is your right to change your mind later. You are free to withdraw from the project at any time. 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 [insert Institution].

7 What are the alternatives to participation?

You do not have to be in this research project to receive treatment at this clinic. Other options to prevent HIV include: advice and counselling on safe sex practices including the use of condoms, and regular HIV and STI testing. HIV post-exposure prophylaxis (PEP) is available at your clinic after any

sexual or injecting exposures that may have put you at risk of getting HIV. 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.

Other anti-HIV medications are currently being studied for use as PrEP. However, no other medications have been approved for the prevention of HIV.

8 What are the possible benefits of taking part?

There is no guarantee or promise that you will receive any benefits from being in this research project. Research shows that taking TRUVADA every day, combined with safer sex practices including using condoms during sex, may decrease your risk of getting HIV. Some participants may experience direct health benefits due to testing for HIV and STIs more regularly than they would normally otherwise. Participants may also like the idea that they are contributing to new knowledge about the prevention of HIV.

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

Medications often cause side effects. You may have none, some, or all of the effects known to be associated with the use of TRUVADA and listed below. 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 the best way of managing any side effects with you.

Possible Side Effects of TRUVADA

TRUVADA has not been used in HIV negative people as much as it has been used in people who are HIV positive. In people who are HIV negative, it has only been used by several thousands of participants in clinical trials of PrEP and by HIV negative people taking it as part of Post-Exposure Prophylaxis or PEP. The dose of TRUVADA used in PEP and PrEP is the same, and in both cases it is taken as a daily tablet. People who take TRUVADA for PrEP and PEP usually take TRUVADA for shorter periods of time than those who take TRUVADA for HIV treatment. As well, people who take TRUVADA for HIV treatment most often take more than one HIV medication at the same time.

I**n people who did not have HIV and took TRUVADA for PrEP:** In previous research studies, between three and nine percent of such participants reported the following four side effects, and these levels were higher than among the participants who did not take TRUVADA (took a “sugar pill”):

- headache
- stomach pain
- involuntary weight loss
- nausea or upset stomach

In PrEP studies where these side effects were reported, these were modest, usually only occurred in the first one or two months of taking the drug and did not last.

In people who *have* HIV who took TRUVADA: the most common (reported in 10 percent and greater) side effects according to the company that makes TRUVADA are:

- diarrhoea
- nausea/upset stomach

- tiredness
- headache
- dizziness
- depression
- difficulty sleeping
- strange dreams
- rash

Possible allergic reaction: In clinical trials of TRUVADA, a small number of people have had an allergic reaction to tenofovir, one of the drugs in TRUVADA. Symptoms of an allergic reaction may include fever, rash, upset stomach, vomiting, loose or watery stools, stomach pain, achiness, shortness of breath, a general feeling of illness or a potentially serious swelling of the face, lips, and/or tongue.

The company that makes TRUVADA also warns that the following changes in laboratory tests are possible. This information is based mostly on experience with people who take TRUVADA for HIV treatment, and on other drugs that are like TRUVADA. Because HIV by itself can also cause these same problems, it is difficult to know how much TRUVADA alone contributes to kidney and bone disease:

- kidney problems
- decreases in the minerals in their bones
- build-up of lactic acid in the blood
- enlarged liver

Because the last two of these side effects are so serious, the symptoms of each are listed below. **Call your doctor immediately if you get these symptoms:**

Symptoms of too much lactic acid in the blood	**Symptoms of severe liver problems**
• weakness or being more tired than usual • unusual muscle pain • being short of breath or fast breathing • nausea, vomiting, and stomach-area pain • cold or blue hands and feet • feel dizzy or lightheaded • fast or abnormal heartbeats	• your skin or the white part of your eyes turns yellow • dark “tea-colored” urine • light-colored stools • loss of appetite for several days or longer • nausea • stomach-area pain

To manage kidney and liver health: Your doctor will be taking blood tests to check you kidneys and liver before you start and while you are taking TRUVADA. Your study doctor may tell you to stop taking TRUVADA if you develop kidney or liver problems during the study.

Bone health:

People who have HIV infection have usually taken anti-HIV treatment for long periods of time and have taken more than one HIV medication including the type of drugs that are in TRUVADA. They have experienced a three- to four-percent decline in the minerals in their bones.

In HIV negative people on TRUVADA bone scans were taken only in two other PrEP research studies – one using TRUVADA and one using one out of the two drugs that make up TRUVADA. These scans found that less than one percent of study participants tested experienced a small decrease in the minerals in their bones during the first few months of PrEP. This decline either stopped getting worse or returned to normal after the first few months. No increase in bone breaks was observed. Because of this, bone scans are not recommended for HIV negative people in this study. However, if

you have a history of bone fractures/breaks or if you are at significant risk for osteoporosis, please tell the study doctor, who will help you manage this risk.

HIV infection

People with HIV need full HIV medication and treatment. You will have an HIV test at every follow-up visit. If you become infected with HIV, your study doctor will have you stop taking PrEP immediately. This is because taking TRUVADA by itself when you have HIV can make the virus resistant to some HIV drugs so that they may no longer work for you and limit your HIV treatment options over time.

Hepatitis B infection

If you become infected with Hepatitis B while you are taking TRUVADA, please tell your study doctor immediately, and do not stop taking TRUVADA on your own. If you stop TRUVADA while you have Hepatitis B, your hepatitis symptoms may get worse. You study doctor will help you stop taking TRUVADA and will monitor you for safety.

Pregnancy and breastfeeding

The effects of TRUVADA on an unborn child and on a newborn baby are not known. You may not participate in this study if you are breast-feeding at the start of the study. If you are female and you can possibly get pregnant, you must also take a pregnancy test at every follow-up visit. All participants are expected to continue use of safer sex practices [non-Catholic sites may add: including the use of condoms].

Any participants who are taking PrEP in conjunction with conception must take daily doses of TRUVADA beginning one month before a conception attempt. TRUVADA must continue to be taken daily until one month after the last attempt to conceive.

Women who become pregnant while in this study should make an informed decision about whether or not to keep taking PrEP while pregnant. If you become pregnant during this study, you should tell your study doctor immediately. Your study doctor will discuss with you your risks of HIV infection during pregnancy, the possible risks of TRUVADA on your pregnancy and child, and whether or not you should stay in the study.

If you become pregnant, we will ask for copies of or access to the parts of your medical records that discuss your pregnancy, delivery, and your infant's health.

Other risks

Having a blood sample taken may cause some discomfort, pain or bruising. Sometimes, the blood vessel may swell, or blood may clot in the blood vessel, or the spot from which blood is taken could become inflamed. Some people may feel dizzy 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.

You may experience pain or discomfort from the rectal or cervical swab. In some cases, you may have some bleeding.

The questions we will ask you about your sexual behaviour may make you feel uneasy. However, you do not have to answer any question that you do not want to and you can stop answering the questions at any time.

Although your information will be kept confidential by study staff, it is possible that your friends, family or people in your community may find out that you are in this study. If that happens, you may experience stigma as a result of being involved in a study about HIV. If this or any other issue may make you become upset or distressed, 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.

10 What will happen to my samples?

Your blood will be collected at the beginning of the study and at follow-up visits, to check your kidney and liver health, and to test for HIV, STI and hepatitis B infection. This is considered routine care for people who take TRUVADA for PrEP. The study team will know that these samples belong to you as they will be sent to the lab with your personal information, as they normally are for routine care.

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.

As mentioned before, 25 millilitres (ml) blood may be collected at some of the follow-up visits, to measure the amount of TRUVADA 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 the PrEP medication. Analyses of the cumulated samples will be conducted at the midpoint and/or the end of the study period.

For these tests, your study ID number, date of birth, and a 2 x 2 name code (first two letters of your first name – first two letters of your last name) will be placed on your sample tubes and the form the site uses to document your blood draw. The ID number can be linked back to you by using a decoding key, which will be stored separately and only known to an authorized member/s of the research study team. The study researchers will be able to link your sample results to your other data by using your study ID number. These samples of your blood will be transferred twice. First, they will be sent to the St Vincent's Centre for Applied Medical Research laboratory for processing. This laboratory will be able to see your ID number, your date of birth and your name code (2 x 2 code comprising first two letters of participant's first name – first two letters of subject's surname). This laboratory must comply with all confidentiality requirements. The samples will then be sent to the Clinical Pharmacology Analytical Lab (CPAL) at the Johns Hopkins University School of Medicine, Baltimore Maryland, USA, for analysis of the level of TRUVADA present. This laboratory will be able to see only your study ID number, but not your date of birth or name code.

You will be asked to provide additional consent for the collection and storage of your blood for banking purposes.

11 What if new information arises during this research project?

Sometimes during a research project, new information becomes available about the medication that is being studied. If this happens, your study doctor will tell you about it and will discuss with you whether you want to continue. 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 may be asked to sign an updated consent form that has the new information in it.

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 TRUVADA will affect any other medications you may be taking. 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 time in the research project. Your study doctor will explain to you which treatments or medications cannot be used if you are involved in the PRELUDE study.

13 What if I withdraw from this research project?

If you decide to withdraw from this project, please let a member of the research team know before you do so. This will allow you to find out about any possible health risks or special requirements before you stop.

If you do withdraw your consent during this research project, the study team will ask you to continue to complete the attitude, behavioural and lifestyle questionnaires online. All the personal information that they have already collected for this study will be kept so 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 PRELUDE study.

If you choose to stop taking PrEP, you can still agree to complete the discontinuation and 3 months post-discontinuation follow-up visits, to complete discontinuation and post-discontinuation online surveys, and/or to allow the team to check your HIV status six months after you discontinue. If you agree to any of these activities after you stop PrEP, please do not complete the revocation of consent form until these follow-up activities are completed.

14 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for reasons which may include:

- Unacceptable side effects
- PrEP being shown not to be effective
- Decisions by local regulatory/health authorities.

15 What happens when the research project ends?

PrEP will be available to you for up till the end of the study. At the present time TRUVADA is not registered for use in Australia. At the end of this study Gilead Sciences may not agree to continue to supply TRUVADA, or may agree to provide an ongoing supply but only under certain conditions and for a limited time period. At the end of the study, if the study drug is still not registered in Australia AND subsidised on the PBS for your condition, then [*insert study site name*] will not be able to fund ongoing supplies of the drug. TRUVADA may never be registered in Australia for PrEP. This means that TRUVADA may not be available or may be expensive for you to buy. Your study doctor will discuss with you other options to help prevent HIV infection.

We estimate that all participants in the study will have completed the study by the end of 2018. After this time, 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?

How information is used and stored

By signing the consent form you agree to let the study doctor and related research staff collect and use personal information about you for the research project. Any information collected for this research project that can identify you will remain confidential.

Information collected for this research will be kept in two different databases:

Health information: Health information collected about you for this research will be entered into and stored in a study-specific password-protected database. This information will be coded, which means that your name won't be included. However, the study staff can link this information back to the rest of your personal information, such as your clinic medical records or Commonwealth and State agency health and disease-related registries, by using a decoding key containing your date of birth. Your research health information may also be recorded in your health records at the clinic. If at any time during the study your study doctor requests additional HIV testing beyond the standard screening test, copies of these additional test results will be collected so that the researchers can better understand the HIV testing processes involved with PrEP management. Your name and all identifying information will be blocked out and your study ID number will be written on any photocopies collected by the researcher.

Behavioural survey information: Only the researchers at the Kirby Institute will have access to your internet-based survey information. This information will be stored in a password-protected database (SurveyGizmo), and will be treated as confidential and securely stored. All participants will be allocated a study number, and all electronic data will be stored under this code, so your name and identifying information will not be stored with the information collected about you during the study. The behavioural survey system will store your preferred email address so that the system can send you invitations to compete the surveys, and automatic reminders if you do not complete a survey within the prefered time frame. Your email address is stored separately from your clinical information. Your name is not stored in any database.

All electronic databases kept at the Kirby Institute will be protected by passwords and University of New South Wales firewalls. Identifying details (such as your name and contact details) and the fact that you are participating in this study will be known only to: your doctor; the research nurse/s at your clinic; and the project leader and research assistant based at the Kirby Institute, UNSW, Sydney. The project leader and research assistant at the Kirby Institute will need your name and contact details so as to assist with follow-up and provide you with information about the study as it progresses.

The researchers at the Kirby Institute will not share any of your survey answers with your clinic doctors, nurses or other staff. However, if you do not complete a behavioural survey within the preferred time frame nor after you have received two electronic reminders, the Kirby Institute researchers may ask the study staff to contact you to provide another reminder.

Any paper based forms used for this study 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.

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.

Any information obtained for the purpose of this research project and for any future related research described in Part 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.

Inspection of research records

It is possible that your health research study records may be inspected in order to make sure that the study is being conducted appropriately and safely, and that the information is being reported truthfully. Possible inspectors include: representatives from the Kirby Institute, relevant authorities and authorised representatives of the Kirby Institute, the institution relevant to this Participant Information Sheet, *[Name of institution],* or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to these relevant study personnel and regulatory authorities.

Publication and presentation of research findings

The findings from this research project will be published and/or presented in a variety of places, most likely combined with everyone else's information. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

Your rights to your information

In accordance with relevant Australian and New South Wales 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.

Information storage after the study

After the end of the study, your study files will be archived in a locked storage facility and kept for at least 15 years after the end of the study. Coded data in electronic form will also be stored for this amount of time.

17 Complaints and compensation

If you suffer any injuries or have 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.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from your participation in the study. Compensation from the sponsor of this study, the University of New South Wales, may be available if your injury or complication is caused by the drugs or procedures, or by the negligence of any of the parties conducting the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies.

If you are not eligible for compensation for your injury or complication under the law, but 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.

The people running this study agree to follow the Medicines Australia *Guidelines for Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial*. These Guidelines allow for some claims for compensation to be settled without the need for legal action to be taken. The fact that the people running this study have agreed to abide by these guidelines in respect of the clinical trial does not affect your rights to pursue legal action in respect of any injury you may suffer as a result of participation. You can obtain a copy of these Guidelines from the Secretary of the Human Research Ethics Committee."

18 Who is organising and funding the research?

This research project is being conducted by the Chief Investigator, Dr Iryna Zablotska at the Kirby Institute, and is being funded by the NSW Ministry of Health. The manufacturer of TRUVADA, Gilead Sciences, is providing the study drug.

[*Insert site name*] will receive payments from the NSW Ministry of Health for time spent 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).

Gilead Sciences may benefit financially from this research project if, for example, the project assists Gilead to obtain approval for TRUVADA to be used as PrEP in Australia.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to Gilead Sciences, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

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 St. Vincent's Hospital, Darlinghurst NSW. 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 about 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 study chief investigator Dr. Iryna Zablotska on 9385-0951 or any of the following people:

Clinical contact person (for each study site to complete; may provide more than one if necessary)

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person (for each study site to complete)

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

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	St. Vincent's Hospital Sydney HREC
HREC Reference number	HREC/14/SVH/130
HREC Executive Officer	Contact person - HREC Executive Officer
Telephone	8382 2075
Email	research@stvincents.com.au

Local HREC Office contact (Single Site -Research Governance Officer – for each study site to complete)

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

Consent Form

Title	Implementation of HIV preexposure prophylaxis with antiretroviral medications among people at high risk for HIV infection: A demonstration project
Short Title	The PRELUDE Study
Protocol Version	30 September 2015
Protocol Number	HEPP 1403
Project Sponsor	The Kirby Institute for Infection and Immunity in Society
Coordinating Principal Investigator	Dr. Iryna Zablotska, The Kirby Institute
Associate Investigator(s)	[insert if required by institution]

Declaration by Participant: Consent to be in the PRELUDE Study

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 *[Insert site name here]* concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I give permission to link my details using a unique identifying code with the Commonwealth and State agency health and disease-related registries. Such registries include, but are not limited to, registries of HIV, STIs and use of HIV post-exposure prophylaxis. This information will allow more accurate ascertainment of HIV and STI diagnoses, as well as the use of the antiretroviral medications outside of the demonstration project PRELUDE.

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.

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, the investigator/sponsor will request my permission to access my medical records for collection of follow-up information for research and analysis.

Please ***initial*** one option for the following (yes or no):

I agree that the Kirby Institute may contact me about future research projects that I may qualify for.

(initial one option) _____Yes _____No

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.

Declaration by Study Doctor/Senior Researcher

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† (please print) _____

Signature _____ Date _____

† 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	Implementation of HIV preexposure prophylaxis with antiretroviral medications among people at high risk for HIV infection: A demonstration project
Short Title	The PRELUDE Study
Protocol Version	30 September 2015
Protocol Number	HEPP 1403
Project Sponsor	The Kirby Institute for Infection and Immunity in Society
Coordinating Principal Investigator	Dr. Iryna Zablotska, The Kirby Institute
Associate Investigator(s)	[insert if required by institution]

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 Study Doctor/Senior Researcher will need to provide a description of the circumstances in the participant's source documentation.

Declaration by Study Doctor/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 Study Doctor/
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.

Appendix III PRELUDE Blood Banking Participant Information and Consent Form Template

[Clinic Logo] 

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

BLOOD SAMPLE COLLECTION AND STORAGE

St Vincent's Centre for Applied Medical Research Biobank

Title	Implementation of HIV preexposure prophylaxis with antiretroviral medications among people at high risk for HIV infection: A demonstration project
Short Title	The PRELUDE Study
Project Sponsor	The Kirby Institute for Infection and Immunity in Society
Coordinating Principal Investigator	Dr. Iryna Zablotska, The Kirby Institute
Associate Investigator(s)	*[Site: insert if required by institution]*

Request

You are invited to take part in the optional collection and storage of extra blood samples because you are a participant in the PRELUDE Study.

We ask that you consider giving your permission for storage of a sample of your blood at the St Vincent's Centre for Applied Medical Research laboratory for possible use in future 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 friend, partner, family member or your doctor.

Participation in this optional 'blood banking' is voluntary. If you don't wish to take part, you don't have to. Should you choose not to participate in this optional "blood banking" component, this will not affect your participation in the main study.

This form provides you with information to help you decide whether you will allow this.

What kind of sample will be taken, and how?

As part of the main PRELUDE Study, you will have an extra sample of blood taken for storage at the one-month follow-up visit, and later at months 6, and 12 (about ten millilitres or two teaspoons). This will be collected by a trained nurse from a vein in your arm. If you take a break from taking TRUVADA® for any reason, this schedule may change to accommodate that break. However, you will have no more than three collections of this blood during the study,

The blood will be processed in a laboratory. The remaining substance, called serum, will then be stored for possible future research use.

If you agree to participate in this blood sample storage sub-study, you will be consenting to allowing the blood samples to be stored and analysed beyond the end of the PRELUDE Study. The samples will be stored indefinitely.

2. 'Will the sample be identifiable as mine after it is stored?'

Your personal identifiers, such as your full name and date of birth, will be removed, and this will be replaced with a unique code on all sample labels. However, these stored tissue samples could be re-identifiable as yours.

Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law.

All participants will be allocated a study number, and all electronic data will be stored under this code, so your name and identifying information will not be stored with the information collected about you during the study. All electronic databases kept at the Kirby Institute will be protected by passwords and University of New South Wales firewalls. Identifying details (such as your name and contact details) and the fact that you are participating in this study will be known only to: your doctor; the research nurse/s at your clinic; and the project leader and research assistant based at the Kirby Institute, UNSW.

3. 'What will happen to my sample?'

Your sample will be stored at the St Vincent's Centre for Applied Medical Research Biobank, Sydney, indefinitely.

We wish to store (or 'bank') the sample for potential, and as yet unspecified, research in the future. Not all potentially beneficial future research can be known at any one time, as the need for future research is determined by ongoing developments in the field. If you agree to your sample being stored, you will be asked to sign a specific consent form to store your sample in this way.

4. 'How will I know if my samples are being used in the future?'

If you agree to your sample/s being stored for future research, they may be used for research projects in the future with the approval of a Human Research Ethics

Committee. The information obtained from future tests will not reveal anything about your health status. Therefore, neither you nor your doctors will be contacted by the Researchers in connection with the research or any information about the results of tests performed on the sample that you donate for this sub-study.

It may be possible to provide you with feedback about the findings of potential future research, should you agree to be contacted by the Kirby Institute when the study is completed.

5. 'Who will have access to my tissue sample once it has been stored?'

The research team responsible for ensuring appropriate standards are met in storing and managing your specimens will have access to your sample/s. Researchers involved in research approved by a Human Research Ethics Committee may also have access to your sample.

6. 'Will drug or biotechnology companies be able to use my sample for profit in the future?'

There is the possibility that research involving your blood sample may result in commercially viable technology or treatments. You will not however be able to claim financial benefit from any discoveries arising from the use of your sample.

7. 'How long will my tissue sample be stored?'

Your sample will be stored indefinitely.

8. 'Will I be able to get my sample back if I change my mind once it has been stored in the 'tissue bank'?'

You may contact your study doctor at any time and request that your sample be destroyed, where this can be done.

9. 'Who should I contact if I have concerns about the conduct of this study?'

This study has been approved by St Vincent's Hospital HREC. Any person with concerns or complaints about the conduct of this study should contact the

Research Office who is nominated to receive complaints from research participants. You should contact them on 02 8382 2075 and quote HREC/14/SVH/130.

The conduct of this study at the [*name of site*] has been authorised by the [*name of organisation*]. Any person with concerns or complaints about the conduct of this

study may also contact the [*Research Governance Officer* or *other officer*] on [*telephone number*] and quote reference number [*insert SSA reference number*]

Thank you for taking the time to consider this study. If you wish to take part in it, please sign the attached consent form. This information sheet is for you to keep.

[Clinic Logo]

BLOOD SAMPLE COLLECTION AND STORAGE
[To be used in conjunction with a Participant Information Sheet]

St Vincent's Centre for Applied Medical Research Biobank

Title	Implementation of HIV preexposure prophylaxis with antiretroviral medications among people at high risk for HIV infection: A demonstration project
Short Title	The PRELUDE Study
Project Sponsor	The Kirby Institute for Infection and Immunity in Society
Coordinating Principal Investigator	Dr. Iryna Zablotska, The Kirby Institute
Associate Investigator(s)	*[Site: insert if required by institution]*

1. I,.....
of.....
agree to donate my blood/tissue as described in the Participant Information Sheet set out above***.***

2. I acknowledge that I have read the Participant Information Sheet, which explains why I have been asked to donate blood/tissue. The nature and risks of this blood sample storage bank have been explained to me to my satisfaction.

3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.

4. I understand that I ***may*** be able to request my stored samples be destroyed, and this will not prejudice to my relationship to the Kirby Institute, the University of New South Wales, [insert site name], St Vincent's Centre for Applied Medical Research Biobank, or my doctor.

5. I agree that research data gathered relating to my samples may be published, provided that I cannot be identified.

6. I understand that if I have any questions relating to my participation in this tissue bank, I may contact [Clinician's name].on telephone [insert telephone number]., who will be happy to answer them.

7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Sheet.

Please ***initial*** one option for the following (yes or no):

I wish to be contacted with feedback about the findings of potential future research that is done using my banked samples.

(initial one option) _____Yes _____No

Complaints may be directed to the, Research Office on 02 83822075

Signature of participant	**Please PRINT name**	**Date**

Signature of witness	**Please PRINT name**	**Date**

Signature of investigator	**Please PRINT name**	**Date**

[Clinic Logo]

BLOOD SAMPLE COLLECTION AND STORAGE

St Vincent's Centre for Applied Medical Research Biobank

Title	Implementation of HIV preexposure prophylaxis with antiretroviral medications among people at high risk for HIV infection: A demonstration project
Short Title	The PRELUDE Study
Project Sponsor	The Kirby Institute for Infection and Immunity in Society
Coordinating Principal Investigator	Dr. Iryna Zablotska, The Kirby Institute
Associate Investigator(s)	*[Site: insert if required by institution]*

REVOCATION OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the blood sample storage bank described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the Kirby Institute, the University of New South Wales, [insert site name], St Vincent's Centre for Applied Medical Research Biobank, or my doctor.

Signature Date

Please PRINT Name

The section for Revocation of Consent should be forwarded to **(INSERT name and full address of Principal Investigator).**