

CONSENT FORM

NZ PrEP STUDY

AT AUCKLAND REGIONAL SEXUAL HEALTH SERVICE (ARSHS)

Request for Interpreter:

Circle One

English: <i>I wish to have an interpreter</i> _____	Yes	No
Deaf: <i>I wish to have a NZ sign language interpreter</i> _____	Yes	No
Māori: <i>E hiahia ana ahau ki tētahi kaiwhaka māori/kaiwhaka pakeha korero</i> _____	Ae	Kao
Cook Island Māori: <i>Ka inangaro au i tetahi tangata uri reo</i> _____	Ae	Kare
Fijian: <i>Au gadreva me dua e vakadewa vosa vei au</i> _____	Io	Sega
Niuean: <i>Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu</i> _____	E	Nakai
Samoaan: <i>Ou te mana'o ia i ai se fa'amatala upu</i> _____	loe	Leai
Tokelaun: <i>Ko au e fofou ki he tino ke fakalliu te gagana Peletania ki na gagana o na motu o te Pahefika</i> _____	loe	Leai
Tongan: <i>Oku ou fiema'u ha fakatonulea</i> _____	lo	Ikai

- I have read, or have had read to me in my first language, and I understand the Participant Information Sheet dated 31st of August 2016.
- I have been given enough time to consider whether or not to take part in this study.
- I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.
- I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.
- I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.
- I consent to the research staff collecting and processing my information, including information about my health.
- If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.
- I understand my taking part in this study will be part of my medical record and I consent to my GP or current provider being informed about my taking part in the study and this includes any medication or test results obtained during the study.
- I understand that my taking part in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.
- I understand the compensation provisions in case of injury during the study.
- I know who to contact if I have any questions about the study in general.

It has been explained to me that: *(check all as understood and agreed)*

- I understand that I must take my PrEP medication every day for it in order to best protect me from getting HIV infection.
- I understand that PrEP does not give 100% protection from HIV infection.
- I understand that PrEP does not prevent other STIs (sexually transmitted infections) so I have been advised to use condoms as well as taking PrEP. I understand PrEP may cause side effects so I should contact the sexual health clinic promptly for advice by calling 0800739432 if I have any health problems I understand it is important for my health to find out quickly if I get HIV infection while taking PrEP so I will contact the sexual health service immediately if I get symptoms or if it is after-hours or the weekend I will go to the nearest hospital emergency department.
- I agree to attend the sexual health service every 3 months for blood and STI testing while I am taking part in the PrEP study.
- I agree to completing the on-line behavioural survey within 3 days of each study visit or when reminded by sexual health staff.
- I agree not to share my PrEP medication with any other person.
- I understand that the PrEP treatment will be stopped if it should appear harmful to me.
- I understand that if I choose to withdraw from the study I will no longer have access to free PrEP medication.

I wish to receive a copy of the results and/or I would like the researcher to discuss the outcomes of the study with me _____ Yes No

Please be advised that a significant delay may occur between data collection and publication of the results.

I _____ (full name) hereby consent to take part in this study.

Signature _____ Date _____

Whānau/Family/Significant Other's signature:

Name _____ (Please print)

Signature _____ Date _____

Interpreter:

Name _____ translated the project to the participant.

Signature _____ Date _____

Declaration by Auckland Regional Sexual Health Service staff member:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it. I believe that the participant understands the study and has given informed consent to participate.

Staff Name and Role _____

Signature _____

Full names of researchers: Dr Sunita Azariah, Dr Peter Saxton, Nurse Specialist Suzanne Werder, Jordon Harris, Dr Rick Franklin, Mark Fisher, Nick Laing, Rose Forster

Contact phone number for researchers: 0800 739 432