VAX-PLORE Study – Participant Information Statement

Title:	The VAX-PLORE Study: Investigating COVID-19 vaccine acceptability among people living with HIV (PLHIV) and people taking HIV pre-exposure prophylaxis (PrEP)
Short Title:	VAX-PLORE
Protocol Number:	77/21
Project Sponsor	Alfred Health
Coordinating Principal Investigator/ Principal Investigator	Associate Professor Edwina Wright

Introduction

You are invited to take part in this research project, which is called VAX-PLORE.

This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part. Participation in this study is voluntary.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about.

By giving consent to take part in this study you are telling us that you:

- Understand what you have read.
- Agree to take part in the research study as outlined below.
- Agree to the use of your personal information as described.

You can download or print a copy of this Participant Information Statement to keep.

What is the purpose of this research?

This study is investigating people's willingness to be vaccinated against COVID-19. The study will identify attitudinal and socio-demographic factors associated with vaccine acceptability, and explore differences in vaccine acceptability between two specific populations: a) people living with HIV (PLHIV); b) and current/previous users of HIV pre-exposure prophylaxis (PrEP). The results will help inform the development of health-promotion activities related to COVID-19 vaccines.

In addition, the study will investigate the impact of the COVID-19 pandemic on people living with HIV (PLHIV) and people taking HIV pre-exposure prophylaxis (PrEP) with a particular focus on experiences of sex, relationships and clinical care during this period.

You have been invited to participate because you are either: a person living with HIV (PLHIV); or a current/previous user of HIV pre-exposure prophylaxis (PrEP). To participate you must also be aged 18 years or above, and currently (or usually) reside in Australia.

What does participation in this research involve?

If you decide to take part in this research, we will ask you to complete an online questionnaire. The questionnaire includes questions about your current health status; vaccination history; COVID-19 testing history; and attitudes towards COVID-19 vaccines and COVID-19 in general, as well as basic demographic information.

If you are a person living with HIV, we will then ask you to complete an additional part of the questionnaire that includes questions about your experiences of HIV clinical care and treatment (including changes as a result of the COVID-19 pandemic), your mental health and well-being, your alcohol and drug use, and your experiences of sex and relationships since the start of the COVID-19 pandemic.

If you are a person who has either currently or previously used PrEP, we will then ask you to complete a different part of the questionnaire that includes questions about your experiences of PrEP (including changes as a result of the COVID-19 pandemic), your mental health and well-being, your alcohol and drug use, and your experiences of sex and relationships since the start of the COVID-19 pandemic.

At the end of the questionnaire, you will also be asked if you would like to be contacted in the future about the possibility of enrolling in a clinical study measuring immunological responses to COVID-19 vaccines.

There are no costs associated with participating in this research project, nor will you be paid.

Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine care, your relationship with professional staff or your relationship with the researchers or anyone else at Alfred Health.

Do I have to take part in this research project?

There will be no clear individual benefits to you as a result of your participation in this research.

What are the possible risks and disadvantages of taking part?

We don't expect the survey questions will cause harm. However, it is possible that reflecting on personal experiences, or issues connected to sexuality – or to HIV diagnosis or risk – could cause distress for some participants.

If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately.

If you experience feelings of distress as a result of participation in this study you can let the research team know and they will provide you with contact details of services that provide free, confidential support.

What if I withdraw from this research project?

If you decide to take part in the study and then change your mind later, you are free to withdraw at any time. You can do this by simply closing your browser window. However, your responses to the survey questions up to the point at which you stopped, will be included in the study.

Could this research project be stopped unexpectedly?

As this study only involves completion of a one-off online questionnaire, it is unlikely that this study will be stopped unexpectedly.

What happens when the research project ends?

You can find out about the results of the study by returning to the study website from April 2021 where we will provide a summary report of the results.

You can also register your email address on the website to receive the summary report directly.

What will happen to information about me?

Submission of the online questionnaire is an indication of your consent. By clicking the 'I agree to participate' button you are consenting to the research team collecting and using personal information about you for the research project.

Survey data will be collected using REDCap, which is a secure web application for building and managing online surveys and databases. Data entered into REDCap runs on the Alfred Hospital's servers, which provides increased security.

Any information obtained in connection with this research project that can identify you will remain confidential. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Data collected for this study may be used for other purposes in the future if such purposes are closely related to the original project; or are in the same general area of research.

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, except with your express permission.

Any information obtained for the purpose of this research project (and for any future 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.

Who is organising and funding the research?

This research project is being conducted by Associate Professor Edwina Wright (of Alfred Health and Monash University). The other researchers involved in the study are from Alfred Health, Monash University, the Peter Doherty Institute, and the Burnet Institute.

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

theAlfred Caulfield HOSPITAL Sandringham HOSPITAL MSHC MELBOURNE SEXUAL HEALTH CENTRE

Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of The Alfred Hospital.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

Support Services Contact Details

If at any stage during the study, you become distressed or require professional support please contact:

Name/Organisation	QLife (Free National telephone and web counselling for LGBTI people 3pm-12am daily)
Telephone	1800 184 527
Web address	Qlife.org.au

Name/Organisation	Beyond Blue (Free National telephone support 24 hours/7 days a week)
Telephone	1300 224 636
Web address	www.beyondblue.org.au

Name/Organisation	Victorian AIDS Council (for Victorian-based participants)
Telephone	(03) 9865 6700 or 1800 134 840
Web address	thorneharbour.org/lgbti-health/mental-health/counselling
Services	Face-to-face and phone counselling Monday-Friday

Name/Organisation	ACON (for NSW-based participants)
Telephone	(02) 9206 2000
Web address	ACON (LGBTI counselling) acon.org.au/what-we-are-here-for/mental-health/#lgbti-counselling ACON (HIV counselling) acon.org.au/what-we-are-here-for/mental-health/#hiv-counselling
Services	Substance-support counselling (Face-to-face and phone counselling; Monday–Friday)

Further information

If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact:

A/Prof Edwina Wright Ph:+61 3 9076 6078 or edwina.wright@monash.edu

Or any of the following people:

Dr Dean Murphy Ph: +61 4 00 380 488 dean.murphy@alfred.org.au

Dr Vincent Cornelisse Ph: +61 4 78 617 179 vincent.cornelisse@health.nsw.gov.au

Complaints

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact The Office of Ethics and Research Governance using the details outlined below. Please quote the study title and protocol number.

research@alfred.org.au

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