ONLINE PARTICIPANT INFORMATION STATEMENT

A virtual cohort to measure monkeypox vaccine uptake and efficacy
TraX: Tracking the community response to monkeypox

Professor Andrew Grulich & Dr Mohamed A. Hammoud

1. What is the research study about?

Since May 2022, a large outbreak of monkeypox (MPX) has spread to many countries around the world, mostly in gay, bisexual, and other men who have sex with men. In Australia, a vaccine is being targeted towards those at risk. The research study aims to investigate monkeypox (MPX) vaccine uptake and real-world effectiveness in Australia.

You are invited to take part in this research study. This study will:

1. Determine the level of previous monkeypox (MPX) infections at the study starting point and measure the monkeypox (MPX) incidence over the 12 – 18-month follow-up period.
2. Determine the effectiveness of vaccine dosing strategies.
3. Measure rates and predictors of vaccine uptake.
4. Measure the severity of monkeypox (MPX) infection which occurs before and after vaccination.
5. Identify under-vaccinated, at-risk populations to guide effective public health responses to monkeypox (MPX).

2. Who is conducting this research?

The study is being carried out by the researchers at the Kirby Institute UNSW, research partners, and the NSW Department of Health.

Co-Principal Investigators

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Coordinating Investigators

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Co-investigators

- Professor Anthony Kelleher. Kirby Institute, Faculty of Medicine, UNSW Sydney.
- Professor Raina MacIntyre. Kirby Institute, Faculty of Medicine, UNSW Sydney.
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- Professor Gail Matthews. Kirby Institute, Faculty of Medicine, UNSW Sydney.
- Dr Nicholas Medland. Kirby Institute, Faculty of Medicine, UNSW Sydney.
- Dr Fengyi (Jeff) Jin. Kirby Institute, Faculty of Medicine, UNSW Sydney.
- Dr Benjamin Bavinton. Kirby Institute, Faculty of Medicine, UNSW Sydney.
- Professor Martin Holt. Centre for Social Research in Health, UNSW Sydney.
- Dr Vincent Cornelisse. Medical Unit Manager, Kirketon Road Centre.
- Professor Matthew Law. Kirby Institute, Faculty of Medicine, UNSW Sydney.
- Associate Professor Phillip Read. Kirketon Road Centre.
- Dr Valerie Delpech. New South Wales Ministry of Health.
- Professor Christopher Fairley. Director of the Melbourne Sexual Health Centre.
- Professor Michelle Giles. Alfred Health, The Royal Women's Hospital, Monash Health and Western Health

Associate investigators

- Heath Paynter. Australian Federation of AIDS Councils (AFAO).
- Dr John Rule. National Association of People with HIV Australia (NAPWHA).
- Jane Costello. Positive Life NSW.
- Simon Ruth. Thorne Harbour Health.
- Nicolas Parkhill AM. ACON Health.
- Richard Keane. Living Positive Victoria.
- Matthew Vaughan. ACON Health.
- Mr James MacGibbon. Centre for Social Research in Health, UNSW Sydney.

Research Funder: This research is being funded by the Kirby Institute, UNSW Sydney, and the NSW Department of Health.

3. Inclusion/Exclusion Criteria

Before you decide to participate in this research study, we need to ensure that it is ok for you to take part. The research study is looking recruit people who meet the following criteria:

- Age 18 years or older.
- All people (whether cis or trans men, cis or trans women, or non-binary) who
- Report sex with cis and trans gay, bisexual, and other males or non-binary people who have sex with cis or trans men (GBMSM+) in the preceding 12 months.
- Currently living in Australia.

4. Do I have to take part in this research study?

Participation in any research study is voluntary. If you do not want to take part, you do not have to. If you decide you want to take part in the research study, you will be asked to:

- Read the information carefully (contact us on trax@unsw.edu.au to ask questions if necessary).
- Complete online questionnaires.

5. What does participation in this research require, and are there any risks involved?

If you decide to take part in the research study, we will ask you to complete a brief weekly questionnaire for up to 1.5 years.

Baseline and twice-yearly items: Newly enrolled participants will complete a brief baseline questionnaire. Items relevant to monkeypox (MPX) but not needing to be captured as frequently will be asked at baseline, then every six months. We anticipate this will take up to 10-minutes to complete. The baseline and twice-yearly survey will collect demographic characteristics, monkeypox (MPX) awareness and vaccine history, STI testing and diagnoses, HIV testing among non-HIV positive GBM, use of antiretrovirals as HIV treatment or prevention, and viral load among HIV positive GBM.

We do not collect any data from your clinic medical records.

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Weekly questionnaire: The weekly questionnaire will take up to 2-minutes to complete. Weekly questionnaire items include monkeypox (MPX) testing, vaccination, and diagnosis, and sexual behaviours. Each week on Monday morning, you will receive an email with a link to your weekly questionnaire. Complete your entry by Wednesday night if you want to be in the raffle. We'll send you an email reminder on Tuesday morning if you have not completed your entry. If you provide your mobile number, we'll send you one final text message reminder on Tuesdays at 11 am.

Monkeypox (MPX) diagnosis: If a participant indicates a positive monkeypox (MPX) diagnosis in a weekly questionnaire, additional questions will appear for a four-week period taking up to five-minutes to complete each week. These items include information on symptoms, severity of infection, and type of vaccination.

No information from the vaccination clinic is shared. Information on receipt of MPX vaccination comes from two sources:

1. Self-report by participants.
2. Data linkage through the Australian Immunisation Register in participants who provide optional consent.

We do not extract data on vaccination directly from clinic records.

Data linkage: Consent to data linkage is an optional component of this study. We will seek consent to link data with commonwealth and state agency health and disease-related registries and databases and obtain state-based Population and Health Services Research Ethics Committee approval to conduct data linkage. Such registries include the Australian Immunisation Register, MPX, HIV, and sexually transmissible infections (STI) registries. Consenting participants will be required to provide their full name, date of birth, postcode of residence, and Medicare number (if available).

Weekly raffles: Participants who complete their weekly questionnaire within 48 hours of initial invitation will enter a raffle to win one of four weekly prizes in the form of $50.00 electronic gift cards. Winners will be randomly selected and notified each Thursday by automatically sending a link for their gift cards to the participants nominated email or mobile number.

Possible risks: It is possible that some participants may experience some anxiety by the use of sexually explicit language in the questionnaire, or for providing answers about sensitive, personal information, including HIV status and history of other sexually transmitted infections (STI), sexual partners and behaviours, and health-seeking behaviours. Given the association between the current monkeypox (MPX) outbreak and gay, bisexual, and other men who have sex with men, some participants may also be acutely aware of the potential for stigma associated with monkeypox (MPX). If you experience discomfort or feelings of distress while participating in the research and you require support, you can stop participating at any time by closing the browser. You can also tell a member of the research team and they will provide you with assistance or alternatively a list of support services and their contact details are provided below.

6. What are the possible benefits to participation?

There are no personal or direct benefit of participation. However, the research may provide valuable information to allow government health agencies to rapidly respond to community needs while also informing efforts of government, community and clinical partners with regards to their monkeypox (MPX) response.

7. What will happen to information about me?

By selecting the option “Click here to confirm that you have read and understand the participant information sheet, and you have been provided a downloadable copy of this consent located at www.traxstudy.org.au” a indicates your consent. This confirms you are providing your permission for the research team to collect and use information about you for the research study. The research team will store the data collected from you for this research project for a minimum of 7 years after the completion of the research. All identifying information is stored separately from participants' completed questionnaires. Access to any data or identifying information will be protected by secure barriers at each level of access. The information about you will be stored in a deidentified format where your identify will be unknown. You will be asked to provide your consent for the research team the share or use the information collected from you in future research that:

- Will be specific to the aims of this research;
- Will be an extension of the original project;
- Will be used in any future research.

Your information will only be shared in a format that will not identify you.

8. How and when will I find out what the results of the research study are?

The research team intend to publish and/ report the results of the research. All Information will be published in a way that will not identify you.

If you would like to receive a copy of the results you can let the research team know by inserting your email or mailing address in the consent form. We will only use these details to send you the results of the research.

9. What if I want to withdraw from the research study?

If you do consent to participate, you may withdraw at any time. You can do so by clicking on the ‘withdrawal my consent from the study’ link and completing the form to automatically remove yourself from the study. Alternatively, you can email the research team at trax@unsw.edu.au and tell them you no longer want to participate. Your decision not to participate or to withdraw from the study, will not affect your relationship with the Kirby Institute, UNSW Sydney.
The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by the University, the right to request correction and amendment of it, and the right to make a compliant about a breach of the Information Protection Principles as contained in the PPIP Act. Further information on how the University protects personal information is available in the **UNSW Privacy Management Plan**.

10. What should I do if I have further questions about my involvement in the research study?

The person you may need to contact will depend on the nature of your query. If you require further information regarding this study or if you have any problems which may be related to your involvement in the study, you can contact the following member/s of the research team:

Research Team Contact

Name	Dr Mohamed A. Hammoud
Position	Group Leader and Research Fellow
Telephone	+61 2 9385 9942
Email	mhammoud@kirby.unsw.edu.au

If at any stage during the study, you become distressed or require additional support from someone not involved in the research please call:

Contact for feelings of distress

Name/Organisation	Lifeline: Confidential telephone counselling.
Telephone	13 11 14
Website	http://www.lifeline.org.au
Hours:	24 hours a day, 7 days a week

Name/Organisation	QLife: National telephone and web counselling for LGBTI people
Telephone	1800 184 527
Website	http://qlife.org.au
Hours:	3:00 pm to 12:00 am AEST

Name/Organisation	Beyondblue: Phone and web chat support.
Telephone	1800 22 4636
Website	http://www.beyondblue.org.au
Hours:	24 hours a day, 7 days a week

What if I have a complaint or any concerns about the research study?

If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

Complaints Contact

Position	Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	HC220592

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Consent Form – Participant providing own consent

Declaration by the participant

By checking the I agree/start questionnaire option below:

- I understand I am being asked to provide consent to participate in this research study;
- I have read the Participant Information Sheet, or it has been provided to me in a language that I understand;
- I provide my consent for the information collected about me to be used for the purpose of this research study only.
- I understand that if necessary, I can ask questions and the research team will respond to my questions.
- I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members;

☐ Click here to confirm that you have read and understand the participant information sheet, and you have been provided a downloadable copy of this consent located at www.traxstudy.org.au or by clicking here.

Optional consent (consent to data linkage is an optional component to this study).

☐ I give permission to link my details with Commonwealth and State agency health and disease- related registries with the approval of state-based Population and Health Services Research Ethics Committee. Such registries include the Australian Immunisation Register, MPX, HIV, and sexually transmissible infections (STI) registries.. This information will allow the calculation of the rates of monkeypox (MPX), HIV and STI diagnoses in study.
☐ I would like to opt-in for weekly raffles for every survey completed
☐ I would like to receive a copy of the results from the study.
☐ I provide consent to be contacted for future studies.

Name: _____

Address: _____

Email Address: _____

Form for Withdrawal of Participation

I wish to **WITHDRAW** my consent to participate in the research proposal described above and understand that such withdrawal **WILL NOT** affect my relationship with the Kirby Institute, UNSW Sydney. In withdrawing my consent I would like any information which I have provided for the purpose of this research study withdrawn.

Participant Name

Name of Participant (please type)	
Date	

Submit withdrawal of consent