ONLINE PARTICIPANT INFORMATION STATEMENT
The METHOD Study
Garrett Prestage

The following text will be uploaded to UNSW REDCap and displayed to participants electronically withing the REDCap.

The METHOD Study

Exploring the experience of drug use, sex, and wellbeing among gay and bi men, trans women and non-binary people in NSW

1. What is the research study about?

You are invited to take part in this research study. The research study aims to collect information about gay, bisexual men (cis and trans), trans women and nonbinary people who use drugs. The research will also document and evaluate peer led interventions addressing sexualised drug use (SDU) for gay and bisexual men (cis and trans), trans women and non-binary people. Interventions have been developed by ACON, the leading organisation specialising in health and wellbeing for sexuality and gender diverse communities in NSW.

2. Who is conducting this research?

The study is being carried out by the following researchers:

- Associate Professor Garrett Prestage (The Kirby Institute, UNSW)
- Dr. Mohamed Hammoud (The Kirby Institute, UNSW)
- Associate Professor Anna McNulty (Sydney Sexual Health Centre, School of Population Health UNSW)
- Professor Louisa Degenhardt (National Drug and Alcohol Research Centre, School of Population Health UNSW)
- Dr. Dean Murphy (The Kirby Institute, UNSW)
- Professor Lisa Maher (The Kirby Institute, UNSW)
- Dr. Krista Siefried (National Centre for Clinical Research on Emerging Drugs, UNSW)
- Professor Nadine Ezard (National Centre for Clinical Research on Emerging Drugs, UNSW)
- Associate Professor Adam Bourne (Australian Research Centre in Sex, Health and Society, La Trobe University)
- Associate Professor Anthony Schembri, (St Vincent's Hospital Sydney)
- Mr. Nicolas Parkhill (ACON/UNSW)
- Mr. Teddy Cook (ACON/UNSW)

The study is being supported by staff from: ACON (Sydney); Network of Alcohol and Other Drug Agencies and Positive Life NSW, these staff are:

- Mr. Jack Freestone (ACON/UNSW)
- Mr. Neil Fraser (Positive Life NSW)
- Mr. Robert Stirling (Network of Alcohol and Other Drug Agencies)
- Mr. Justin Xiao (ACON)

Research Funder: This research is being funded by the National Health and Medical Research Council

3. Inclusion/Exclusion Criteria

Before you decide to participate in this research study, we need to verify that you are eligible to take part. The research study is looking to recruit people who:

- Identify as:
  - Gay or bisexual (cis and trans)
  - Transgender female
  - Non-binary
- Can communicate in English sufficiently to consent to the study
- Currently live in NSW

Participants who meet the following criteria will be excluded from the study:

- Under the age of 18

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

Participation in this research study is voluntary. If you do not want 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 study at any stage.

If you decide you want to take part in the research study, you will be asked to:

- Read the information carefully and ask questions if necessary;
- Sign and return the consent form;
- Take a copy of the consent form with you to keep (or we will email it to you or provide a web link where this form can be viewed).

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

If you agree to participate in this study, you will be asked to complete the following research procedures.

Screening: Completing the screening measures will determine whether you are eligible to take part and will take approximately five minutes. The screening questionnaire will be administered to you online, on the study website.

A screening questionnaire will ask about:

- your sexual orientation,
- your gender identity,
- whether or not you currently live in NSW,
- whether you can verbally communicate in English.
- Whether or not you have used party drugs within the past 12 months

Baseline questionnaire: A baseline questionnaire will ask you more questions about your identity and your current circumstances. You will also be asked about your behaviours in relation to drug use and sex, your sexual health, mental health, and broader wellbeing. People who report the use of drugs in sexual

contexts will also be asked more questions about their drug use and their current or previous use of alcohol and other dug services.

Interventions: Those who report use of drugs in sexual contexts in their baseline survey will be invited to complete voluntary interventions. Participants may choose to complete both online interventions and peer to peer interventions if they wish, participants do not have to participate in interventions to participate in the research. All interventions associated with this study have been developed by ACON.

- **Online interventions:** These are interventions that can be self-complete by the participant. Participants who complete online self-directed interventions will be invited to reflect on the role of drug use in their lives, provided a reflective summary of responses and asked to consider whether or not they wish to change their behaviours around drug use, or access any drug and alcohol services. Online intervention participants will also be directed to harm reduction resources about sex and drugs, they will also have opportunity to additionally complete a peer to peer intervention should they wish. Online interventions can be complete as many times as a participant likes.
- **Peer to peer interventions**: Peer to peer interventions are like online interventions but delivered face to face or via telehealth by trained peers. Peers who deliver peer to peer interventions are people who have lived experience of sexualised drug use, who have been trained to provide brief interventions to address harms related to sexualised drug use and trained to support people to better manage their use or change their patterns of use. Participants who choose to speak to a peer about their drug use will be asked to reflect on their substance use and will be invited to consider whether or not they wish to change their behaviours around drug use or access any drug and alcohol services. Participants who speak to a peer will also be provided referrals to relevant harm reduction and health information. Participants who complete peer to peer interventions can complete more than one intervention subject to the recommendations of peer interventionists at ACON

De-identified data related to your participation in and completion of interventions as well as the content of your interventions will be recorded and kept by the study team.

Follow up surveys: All participants, those who complete interventions and those who do not, will be invited to complete a follow up survey on a quarterly basis for up to two years participants will be invited to participate in a maximum of 8 follow up surveys over 2 years. These follow up surveys will ask similar questions to the baseline survey about drug use, sexual practice, sexual health, mental health, broader wellbeing. Those who report the use of drugs in sexual contexts in their follow up surveys will be invited to participate in the interventions that are outlined above.

Optional Participant for an In-Depth Interview: Consenting participants will be invited to be interviewed in depth. This interview will be conducted confidentially, by phone or online. This interview will be conducted by a trained interviewer, recorded for accuracy, and then transcribed for analysis. All recordings will be destroyed upon transcription. This interview should take 90 minutes on average and will

NOT be required for participation in the online cohort. Interview participants will be interviewed once, with the option of completing one follow up interview. No identifying details from the interview will be used in results or reporting of this study.

You are free to stop the interview at any time. If you withdraw from the research, we will destroy any information that has already been collected.

We do not expect completion of the online questionnaires or the questions asked during the in-depth interview to cause any harm or discomfort. However, 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 assistance. Alternatively, lists of services are provided in the contact details below to assist you if necessary.

A separate consent process will be complete with participants who choose to participate in an optional interview.

Additional Costs and Reimbursement: There are no costs associated with participating in this research project, nor will you be paid. However, upon completing each follow up survey you will receive an invitation to enter a raffle prize draw, with the winner receiving a prize valued at $200.

Psychological Distress: You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. issues covered in the online survey and interviews may induce anxiety related to past experiences. This study asks about some sensitive topics, these include discussions of drug overdose, emergency department admission, drug use and method of administration, sexual consent/assault, HIV/HCV status. If you become upset or distressed because of your participation in the research project, the research team will be able to refer you to appropriate support. Alternatively, several free contactable support services are included at **section 12**. 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.

6. What are the possible benefits to participation?

We hope to use information we get from this research study to benefit others who either identify and gay or bisexual men, trans women or nonbinary. Results from this research will be used to inform health and wellbeing service needs of these populations. Specifically, this research will focus on service needs as they relate to drug use among sexuality and gender diverse communities in NSW.

Part of this research will focus specifically on peer led substance use interventions being delivered by ACON in partnership with Sydney Sexual Health Centre, St Vincent's Hospital, NADA, and Positive Life NSW. By participating in this research participants will get access to these services and resources while helping ACON to refine and improve their services, posing community level benefits to people who use substances.

7. What will happen to information about me?

Your confidentiality will be maintained, and no identifying details will be linked to your responses. At consent, you will be provided with a study identification number that will be used in place of your identifying information. Your information will however be re-identifiable, and confidentiality may be broken if you disclose the intention to harm yourself or others. In this instance your information will be shared with the clinical team at ACON who will follow up as per their routine protocols. Should you be subject to criminal

justice proceedings researchers will be obligated to comply with any requests for information that are made by the court.

All data will be securely saved and is compliant and certified under both the EU-U.S. Privacy Shield and Swiss-US Privacy Shield. All electronic databases will be protected by password and UNSW Sydney firewalls.

Your information will only be used to contact you to complete a questionnaire and is sent from an external database, separate to your responses.

By signing the consent form, you consent to the research team collecting and using 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 publication of research results.

You will be asked to provide your consent for the research team to 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, or closely related to, the original project; or is in the same general area of research.

Currently there are no planned secondary research projects. Any future research to utilise your data in this way will undergo its own secondary ethics approval by the UNSW Human Research Ethics Committee.

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 or any study participant. The research team and partner organisations, ACON will also update their websites or social media pages with results from the study.

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 – even after you have signed the consent, you may withdraw at any time. You can do so by completing the 'Withdrawal of Consent Form' which is provided when you are emailed your consent form. Your decision not to participate or to withdraw from the study will not affect your relationship with the ACON, Sydney Sexual Health Centre, NADA, Positive Life NSW or St Vincent's Hospital Sydeny. If you decide to leave the research study, the researchers will not collect additional information from you. You can request that any information about you be withdrawn from the research project.

10. 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	UNSW Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	HC210304

Alternatively, complaints can be directed to the St Vincent's Hospital Research Office or Human Research Ethics Committee

Complaints contact person

Position	Research Office Manager
Telephone	02 8382 4960
Email	svhs.research@svha.org.au
HC Reference number	ETH11027

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	St Vincent's Hospital, Sydney HREC
Position	Research Officer
Telephone	02 8382 4960
Email	svhs.research@svha.org.au

Research Governance Officer

Name	Research Governance Officer
Position	Research Governance Officer
Telephone	02 8382 4960

Email	SVHS.Research@svha.org.au

11. 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 Details

Name	Mr. Jack Freestone
Position	Manager of AOD Research Programs (ACON) & PhD candidate at UNSW
Telephone	0490 293 481
Email	j.freestone@unsw.edu.au

Chief Investigator

Name	Garrett Prestage
Position	Associate Professor, HIV and Epidemiology and Prevention Program
Telephone	02 9385 0939
Email	gprestage@kirby.unsw.edu.au

12. Support Services

Support Services Contact Details

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

Name/Organisation	**Belinda Rimer / ACON**
Position	Intake Officer
Telephone	02 9206 2000
Email	Acon@acon.org.au

Further support services for all study participants in all Australian states and territories are listed below.

- Lifeline: 13 11 14
- Alcohol & Drug Information Service: 1800 250 015
- Family Drug Support 24-hour line: 1300 368 186
- Suicide Call-back Line: 1300 659 467
- Mental Health Crisis Team: 1300 011 511
- After Hours GP Helpline: 1800 022 222
- NSW Rape Crisis: 1800 424 017
- Sexual Assault Counselling Australia: 1800 211 028
- Sexual Health InfoLink: 1800 451 624
- NSW Housing - Link2Home: 1800 152 152

Consent Form – Participant providing own consent

Declaration by the participant

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- ☐ I understand I am being asked to provide consent to participate in this research 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, study tasks and risks of the research described in the study;
- ☐ Recordings: I understand that the research team will audio record the interviews; I agree to be recorded for this purpose.
- ☐ I provide my consent for the information collected about me to be used for the purpose of this research study only.
- ☐ 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 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;
- ☐ I would like to receive a copy of the study results via email or post, I have provided my details below and ask that they be used for this purpose only;
- ☐ I understand that I will be given a signed copy of this document to keep.
- ☐ I understand that the results of the research will be made available on the websites run by the study team.

Optional consent (not required for study participation)
Please tick these extra aspects of the study if you consent to them.

The additional aspects of this study that are not required for participation are listed below. Your participation in these will remain confidential and will help the study, but you can still participate without agreeing to each of these. Please tick each box to show which item you are consenting to (if you have any questions, please let us know):

- ☐ Contact you to request an in-depth interview (as specified above) consisting of an in person or video interview discussion about issues that are discussed in the questionnaire. (Note this consent is just to contact you, this is not consent for the interview itself)
  Optional best phone number for interview contact:
- ☐ Contact you to participate in future studies.
- ☐ Opt in for half-yearly newsletters.
- ☐ I would like to receive a copy of the study results via email, I have provided my details below and ask that they be used for this purpose only.

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

Declaration by Researcher*

I have given a verbal explanation of the research study; its study activities and risks and I believe that the participant has understood that explanation.

Researcher Signature*

Name of Researcher (please print)	
Signature of Researcher	
Date	

[+]An appropriately qualified member of the research team must provide the explanation of, and information concerning the research study.
Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation

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I wish to **WITHDRAW** my consent to participate in this research study described above and understand that such withdrawal **WILL NOT** affect my relationship with the researcher or organisations who are partner to this research study.

☐ I am withdrawing my consent and I would like any identifiable information collected about me which I have provided for the purpose of this research study withdrawn. I am withdrawing my consent to be contacted to participate in further components of this research. I understand that any information already published and/or not linked to my identity cannot be withdrawn from the research.

OR

I wish **WITHDRAW** my consent to participate in the following **optional components of this research study only** (tick all that apply).

- ☐ Contact to request an in-depth interview consisting of an in person or video interview discussion about issues that are discussed in the questionnaire.
- ☐ Consent to have your data linked to Australian hospitals and registries
- ☐ Contact you to participate in future studies.
- ☐ Opt in for half-yearly newsletters.
- ☐ Receipt of the study results via email.

I understand that such withdrawal **WILL NOT** affect my relationship with any of the researchers or organisations who are partner to this research study.

Participant Name

Name of Participant (please type)	
Date	

The section for Withdrawal of Participation should be forwarded to:

CI Name:	Garrett Prestage
Email:	Gprestage@kirby.unsw.edu.au
Phone:	0293850939
Postal Address:	The Kirby Institute, Wallace Wurth Building, High St, Kensington NSW 2052