

Participant Information Sheet

1. Who is conducting the study?

The study is being carried out by the following researchers:

- Prof Martin Holt, Centre for Social Research in Health, UNSW Sydney
- Prof Andrew Grulich, The Kirby Institute, UNSW Sydney
- Prof Rebecca Guy, The Kirby Institute, UNSW Sydney
- A/Prof Garrett Prestage, The Kirby Institute, UNSW Sydney
- Tim Duck, NSW Ministry of Health
- Johann Kolstee, ACON
- Phillip Keen, The Kirby Institute, UNSW Sydney
- A/Prof Mark Stoové, The Burnet Institute, Melbourne
- Jason Asselin, The Burnet Institute, Melbourne
- Dr Kim Wilson, National Serology Reference Laboratory, Melbourne

This research is supported by a National Health and Medical Research Council Partnership Project grant.

2. Inclusion/exclusion criteria

The following people were eligible to take part in COUNT:

- Participants of the Sydney Gay Community Periodic Survey
- Aged 18 or more
- Male
- Identifies as gay or bisexual or has had sex with a man in the past 5 years
- Regularly participates in the Sydney gay community

3. What does participation involve, and are there any risks involved?

After deciding to participate, you were asked to complete a consent form, and then a recruiter would have assisted you in collecting an oral fluid sample for testing. Your sample and Gay Community Periodic Survey questionnaire were labelled with a unique identifier so they can be matched later. After recruitment, we will send all the samples to the National Serology Reference Laboratory for testing. After the study is completed, the laboratory may keep your sample for reference purposes, but will remove the unique identifier so it cannot be linked to you or your questionnaire.

You had two options on the consent form, depending on whether you wanted to get your HIV test results or not. You could choose either:

1. Anonymous participation (not getting your test result). For participants who do not want their HIV test result, and do not want to provide any personally identifying information. We will link your HIV test result and questionnaire, but you will not be contacted by us, so do not need to provide any contact details. Please note that, if you opted for anonymous participation, you cannot change your mind later and choose to receive your result. It also means that if you receive a reactive (positive) result, we cannot contact you.
2. Confidential participation (getting your test result). For participants who wanted to receive their HIV test result. We will link your HIV test result and questionnaire, and you were asked to provide contact details so we can give you your test result. You were asked to sign the consent form in front of the recruiter, who will witness your signature.

If you opted to receive your HIV test result, we estimate that we will contact you approximately three weeks after your sample has been collected (depending on how many test results we have to process). If you have a mobile phone, we will send you a SMS text message telling you that your results are ready. If your result is nonreactive (HIV-negative) the SMS will tell you your result is 'negative'. The text message will also contain a link to a secure website with more information. If your result is reactive (positive) and you have already been diagnosed with HIV, we will send you a SMS telling you your result is 'positive'. The text message will contain a link to a secure website with more information. If your oral fluid sample returns a reactive (positive) test result and you have not been previously diagnosed with HIV, we will send you a SMS asking you to call us. If we do not hear from you within 24 hours we will call you (and keep trying to contact you until we reach you). We will then ask you to have a confirmatory blood test, to confirm whether you are HIV-positive or not. If you don't have a mobile phone, we will call you on a landline. We will also ask you to give us permission to pass a summary of your HIV test results to your local doctor or clinic, to assist them in confirming your oral fluid test result. We estimate that fewer than 1% of men in the study will need to have confirmatory testing at their clinic. If your result is unclear, we will send you a SMS asking you to call us. If we do not hear from you within 24 hours we will call you.

Please note that we will repeatedly attempt to contact confidential participants for up to one month in order to deliver test results or ask them to attend for confirmatory testing. If your contact details change after participating, please contact the study coordinator, Phillip Keen, on 02 9385 9211 or pkeen@kirby.unsw.edu.au. In cases where you have a reactive test result, have not been previously diagnosed with HIV and we do not hear from you, we will keep trying to contact you until the end of the study (December 2018).

Although highly accurate, the HIV test we will use on your oral fluid sample at the laboratory (like other HIV tests) does not have perfect accuracy. That is why if you get a reactive test result we will ask you to attend your local clinic for confirmatory testing, information and support. If you have any concerns about the oral fluid test's

accuracy, we recommend you seek a conventional HIV test from your doctor or sexual health clinic. Contacts are provided in the Support Services section below.

The oral fluid test, like other HIV tests, will not be able to reliably detect HIV during the first month of infection. If you believe you have been recently exposed to HIV, we recommend that you do not rely on the oral fluid test in this study. Instead, you should seek advice from your doctor or local sexual health clinic.

If you have not been previously diagnosed with HIV, receive a reactive (positive) oral fluid test result in this study and it is confirmed by a blood test at your local clinic, you will be diagnosed with HIV by a doctor. The doctor and clinic will provide you with information, support and access to HIV care. Being diagnosed with HIV is a significant life event and may be highly distressing. If you are concerned about this we recommend you seek advice from your doctor, local sexual health clinic or community organisation. A list of contacts is provided in the Support Services section below.

4. What are the possible benefits to participation?

We hope to use information we get from this research study to improve HIV prevention efforts in New South Wales by identifying gay and bisexual men who may be at risk of undiagnosed HIV. This should benefit others by improving the targeting and delivery of HIV prevention and testing services in New South Wales.

Although you may find it beneficial to receive your HIV test result as a result of participating in this study, we cannot promise that you will receive any direct benefits from this study.

5. What will happen to information about me?

By signing the consent form you agreed to the research team collecting and using information about you for the research study. If you provided us contact details so we can provide you test results, we will store this information on a password-protected server at UNSW Sydney until results delivery is completed. Then your contact information will be removed from any databases that we will use to process the results of the study. Your data will be kept for a minimum of 7 years after the project's completion. We will store information about you in a non-identifiable format on a secure server controlled by the study team at the Centre for Social Research in Health at UNSW Sydney. Only the members of the study team based at UNSW Sydney will have direct access to the dataset.

Your information will only be used for main study analyses, which include calculating the prevalence of HIV and undiagnosed HIV, and assessing the characteristics of people with undiagnosed HIV.

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 complaint 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](#).

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

If you opted for confidential participation, you will be contacted so that you can get your HIV test result within approximately 3 weeks of participating.

The research team intend to publish and report the results of the research study in a variety of ways. All information published will be done in a way that will not identify you. The broader findings of the study will be publicised through gay community media, educational materials from our HIV sector partners and the websites of the Centre for Social Research in Health. If you want to be kept updated about the study's findings, please contact the study coordinator, Phillip Keen, on pkeen@kirby.unsw.edu.au

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

If you consented to participate as a confidential participant, you may withdraw at any time before December 2018 (when the study is completed). By that time, we will have removed your contact information from the study database, so it will not be possible to remove your data. If you participated anonymously, we will not be able to remove your data and test result from the study because we will not be able to identify you.

You can withdraw from the study by contacting the research team and telling them you no longer want to participate. Please contact the study coordinator, Phillip Keen, on 02 9385 9211 or pkeen@kirby.unsw.edu.au or the study lead researcher, Professor Martin Holt, on 02 8385 6410 or m.holt@unsw.edu.au. Your decision not to participate or to withdraw from the study will not affect your relationship with UNSW Sydney or the National Health and Medical Research Council.

If you decide to leave the research study, any identifiable information about you will be withdrawn from the research project, including questionnaire data and HIV test results (which will be deleted from the study database).

8. What should I do if I have further questions?

Please contact either:

Study coordinator, Phillip Keen, on 02 9385 9211 or pkeen@kirby.unsw.edu.au

Lead researcher, Professor Martin Holt, on 02 9385 6410 or m.holt@unsw.edu.au

9. 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 on 02 9385 6222 or humanethics@unsw.edu.au

The reference number for the study is HC17793.

10. Support and information services

If you require additional support from someone not involved in the research please contact any of the following free support services, which specialise in providing advice and support about HIV and sexual health to gay and bisexual men:

ACON (formerly AIDS Council of NSW) (<http://www.acon.org.au/>)

ACON is a community organisation that promotes the health and wellbeing of gay and bisexual men and people living with HIV. It offers information and support services, including counselling and peer support programs. It has a number of offices around New South Wales.

Telephone: 02 9206 2000, free call 1800 063 060

Address: 414 Elizabeth Street, Sydney, NSW 2010 (Sydney office)

NSW Sexual Health Infolink (<https://www.shil.nsw.gov.au/>)

This telephone and internet-based service provides free advice on sexual health and HIV. It is staffed by specialist sexual health nurses. The service can provide you with confidential advice on the telephone and help you find free HIV and sexual health services across New South Wales.

Telephone: 1800 451 624, 9am to 5.30pm, Monday to Friday

Positive Life NSW (<https://www.positivelife.org.au/>)

Positive Life NSW is a community organisation that provides advice, advocacy and referrals for people living with HIV. It offers peer support programs and advice on healthy living, doctors and treatments.

Telephone: 02 9206 2177, free call 1800 245 677

Address: Level 5, 414 Elizabeth Street, Sydney, NSW 2010