Participant Information & Consent Form

Non-Interventional Study - *Adult providing own consent*

St Vincent's Hospital Sydney – NSW Sexual Health Infolink – NSW Ministry of Health

Title	NSW Dried Blood Spot Self-Sampling HIV and Hepatitis C Testing Pilot Program
Short Title	NSW HIV and HCV DBS Testing Pilot
Protocol Number	Version 3.7, 24 Nov 2023
Project Sponsor	NSW Ministry of Health
Principal Investigators	Ms Bianca Prain, Dr Rick Varma, A/Prof Philip Cunningham
Associate Investigators	Prof Jason Grebely, Prof Rebecca Guy, Ms Annabelle Stevens

Part 1 What does my participation involve?

1 Introduction

Thank you for taking part in the **NSW Dried Blood Spot Self-Sampling HIV and hepatitis C Testing Pilot Program** (DBS). Your participation in this study helps us assess how DBS testing can be used to reach priority populations who test infrequently for HIV and hepatitis C. DBS testing is not currently used or approved for routine HIV or hepatitis C testing in NSW health clinics and is being offered here as part of a research study.

This Participant Information Sheet and Consent Form tells you about the study. It explains the tests and procedures involved. Knowing what is involved will help you decide if you want to take part in the study.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

2 What is the purpose of this research?

The purpose of the Dried Blood Spot (DBS) testing pilot is to increase access to HIV and hepatitis C testing by providing people with ways to collect their own blood samples in the comfort of their own home. It offers significant advantages to conventional blood testing such as providing added convenience, privacy and confidentiality.

This study also aims to assess whether DBS is an effective and manageable option for increasing access to HIV and hepatitis C testing among priority populations in NSW. It will also assess who is likely to use the program as well as understanding participants' perspectives on the testing process.

3 What does participation in this research involve?

Dried Blood Spot sample
If you agree to participate in this study, you will be asked to provide consent before registering for the testing kit.

If you agree to participate, you will then be asked to:

- Register your name and contact details, receive a validation code and order a DBS testing kit
- When you receive the kit, check your name and phone number again and write the validation code onto the test card in the testing kit
- If a health care worker is helping you collect the sample, they will write down the kit code)
- Take a finger prick blood specimen and collect it using the test card provided. You need to saturate a minimum of 3 full circles (maximum of 5) with your blood and allow the blood to dry
- Send your DBS test card to the laboratory in the reply-paid envelope
- You will receive your results about 1 week after the test card is received by the laboratory. Samples may be tested at the NSW HIV Reference laboratory in St Vincent's Hospital (Sydney) or by NSW Health Pathology.
- Call the nurse at NSW Sexual Health Infolink 1800 451 624 if you need further information

Standard blood sample (research sub-study)
Because the dried blood spot sample test is only able to be used in research, the researchers want to compare it to a standard blood test to prove that it is comparable. By doing so, the researchers hope to get approval to use the DBS test as an alternative test that can be used in standard clinical care.

If you agree, a healthcare professional would like to collect 5ml (about 2 teaspoons) of blood from a vein in your arm. This sample will be sent to the NSW Health Pathology for a standard hepatitis C test and compared to your DBS sample.

Please note, this is an optional part of the research and you do not have to agree. If you agree to this test, please tick the box to opt-in on the consent form.

4 Will taking part in this study cost me anything, and will I be paid?

Participation in this study will not cost you anything and no payments will be made to participants during the study.

5 Who can have a DBS test?

Participants must be 16 years or older living in NSW, able to provide their independent informed consent, and belong to one of the following groups.

The following people will be offered a HIV test:

- gay and other men who have sex with men,
- people with a transgender history,
- people from countries in Asia, Africa or some countries where HIV is more common, and
- people with current or previous sexual partners from one of the above groups.

The following people will be offered a hepatitis C test:

- people who identify as Aboriginal or Torres Strait Islander
- people who have ever injected drugs,

- people from countries in Africa, the Middle East or some countries where hepatitis C is more common
- people who are currently or have ever been in prison
- people who attend or have attended community corrections services
- people who use or have used drug and alcohol services or mental health services
- people who are or have been homeless

The study will run until 31 December 2024 (unless otherwise extended).

6 What is hepatitis C?

Hepatitis C is a blood borne virus that affects the liver. In Australia the most common form of transmission is through injecting drugs and Aboriginal populations have much higher rates of hepatitis C infection when compared to the broader Australian community. At the end of 2015 there was an estimated 227 000 people living with hepatitis C in Australia,36% of this total were living in NSW.

Viral hepatitis is the leading cause of liver cancer. Getting tested for hepatitis C is important because new hepatitis C treatments are easy to take, safe, and highly effective with 95% cure rate. These new cures mean that hepatitis C elimination in Australia is possible.

Hepatitis C RNA shows active hepatitis C infection. People who have had hepatitis C in the past, and have cleared the infection, naturally or through treatment, will not be detected on an RNA test.

Participants completing a DBS hepatitis C RNA test, who receive a detected result, must consider the results as preliminary only. Confirmatory testing via a standard blood test will be necessary and a copy of these results should be provided to the NSW State Reference Laboratory for HIV (St Vincent's Hospital Sydney). The participant will also be offered counselling support.

7 Governance and roles

This pilot program is a research collaboration led by the NSW Ministry of Health, St Vincent's Hospital Sydney, and NSW Sexual Health Infolink. The NSW State Reference Laboratory for HIV (St Vincent's Hospital Sydney) and NSW Health Pathology are responsible for receiving and testing DBS samples and monitoring the quality of DBS testing compared with standard blood testing methods. Sydney Sexual Health Centre provides clinical governance to NSW Sexual Health Infolink, which is responsible for the provision of results and follow-up of participants. In some locations where participants are assisted to complete a DBS test, the local health district will provide results and clinical governance of the staff. Monitoring and evaluation of the program is overseen by the NSW Ministry of Health with input from the research investigators.

A working group has been established to help guide the pilot program, and features representatives from various Local Health District publicly funded sexual health services, Sydney Sexual Health Centre, the Kirby Institute (UNSW Australia), Sexual Health Infolink, St Vincent's Hospital (Sydney), Justice Health and Forensic Mental Health Network, and NSW Ministry of Health.

8 Do I have to take part in this research project?

Participation in any research project, including this pilot program, 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 time.

Your decision to participate or withdraw will not affect your routine treatment or care, your relationship with those treating you or your relationship with other staff involved in your treatment or care in relation to this pilot program.

9 What if I withdraw from this research project?

There are no penalties or adverse effects in withdrawing from this study. If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason and there will be no consequences to you for your withdrawal. To withdraw, please go to the DBS website and complete the Withdrawal of Participation online form or contact the study Project Coordinator directly (contact details are provided on the last page).

New information about the DBS test may become available during the course of the study. You will be kept informed of any significant new findings that may affect your willingness to continue in the study.

If you do withdraw your consent during the study, no additional information will be collected from you, although information already collected will be kept to ensure that the results of the study can be measured properly and to comply with law. You should be aware that any data collected from you up to the time you withdraw will form part of the study results (data will not contain your identifying details).

10 What are the alternatives to participation?

You do not have to take part in this program to receive testing for HIV or hepatitis C. Other options are available; these include conventional blood tests and rapid tests offered at clinics and other community testing sites. Further information is provided on the DBS website www.DBStest.health.nsw.gov.au to help you decide whether or not this program is for you. You can also discuss your options by talking to a registered nurse at NSW Sexual Health Infolink. Call 1800 451 624.

11 What are the possible benefits of taking part?

Although benefits from participating in this pilot program cannot be guaranteed or promised, likely benefits include greater convenience and reduced stress for people testing for HIV and hepatitis C. By participating in this program, you also have the opportunity to contribute to new knowledge about DBS testing, including how it can be used in NSW in the future.

12 What are the possible risks and disadvantages of taking part?

All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. Despite all reasonable precautions, you could develop some mild medical complications from participating in this study. The known risks of this study are:

Mild discomfort from a finger-prick test is common, though bruising seldom occurs.
- You may experience stress and anxiety while waiting for your DBS and/or follow-up confirmatory test results. Counselling support will be available.
- The DBS test is very accurate. In people with HIV infection, the DBS test will be correct more than 99 times out of every 100 tests. A very small number of tests can give a "false positive result", which means the test result is positive, but the person does not have HIV or hepatitis C infection. This is clarified through further testing.
- A very small number of HIV DBS tests may give a "false negative" result. This means that the DBS test may not detect HIV in a person's blood sample if that person had contracted HIV in the last few weeks. If you think you might be in this situation, call the clinical contact person (contact details below in section 20) to discuss your testing options or speak with your doctor/clinic. If your test result is negative, but you were recently ill or exposed to the risk of HIV infection, repeat testing is advised.

If you agree to provide the optional research venepuncture blood sample, you may find the blood collection uncomfortable, but it rarely results in any significant problems. Side effects from drawing blood may include; discomfort, feeling light headed or faint, bleeding, bruising or formation of a blood clot at the site where the needle enters the body, and in rare cases fainting or infection.

The results of any DBS test detecting HIV or hepatitis C should be considered as preliminary only and will need to be confirmed with conventional laboratory based blood testing. A DBS test result that shows HIV or hepatitis C is therefore called a "detected" result and not a "positive" result. All participants that are informed of having a detected test result will be given information on how to have a full confirmatory blood test through their doctor/clinic. A copy of these results (including CD4 if HIV), will be forwarded to the NSW State Reference Laboratory for HIV (St Vincent's Hospital Sydney), and will also be offered counselling support.

If you participate in the research sub-study (by providing a standard blood sample from a vein in your arm), you will receive results of this standard blood test only. You will not receive the result of the paired DBS sample.

13 What will happen to my blood sample after it has been used?

Samples will be stored at the Reference Laboratory at St Vincent's Hospital in Sydney until HIV and/or hepatitis C testing is performed and will be kept for approximately 12 months beyond the recommendations in the national pathology accreditation guidelines in the event further is required. Samples will then be destroyed following completion of the testing and data collection processes.

Dried blood spot and venous blood samples from the validation sub-study will be sent to Serology & Virology Division, NSW Health Pathology, Randwick (SAViD NSWHP) for testing. Samples will be destroyed following completion of the testing and analysis.

14 How will my confidentiality be protected?

Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. The study Project Coordinator, nurses at NSW Sexual Health Infolink, laboratory and clinic staff involved in DBS testing and treatment, and persons monitoring the conduct of the study on behalf of the St Vincent's Hospital Human

Research Ethics Committee will have access to your identifiable details and results which will be held securely on patient management systems used by South Eastern Sydney Local Health District. Only non-identifiable information will be sent off site and all information will be stored in a secure and encrypted format. Patient medical records will be stored for a minimum of 7 years before they can be securely destroyed.

As this pilot program has the potential to inform other research studies, it is intended that non-identifiable study data will be held on a secure central database and made available for future related research where feasible. Non-identifiable study data will be kept for a period of no more than 15 years after the completion of the pilot program and publication, at which point electronic data will be erased and hardcopy data shredded.

Part 2 How is the research project being conducted?

15 What happens when the research project ends?

It is not known if or when the DBS test used in this study will be available after the study finishes. During the study period and through to its conclusion, the DBS Testing Pilot will be evaluated to see whether DBS testing is feasible and acceptable for future use in NSW.

16 What will happen with the results?

If you give us your informed consent through this document, we plan to discuss the collated results (non-identifiable data only) at study meetings and report the results to the St Vincent's Hospital HREC and NSW Ministry of Health for monitoring purposes. We also plan to publish the results in a peer-reviewed journal and present the results at conferences or other professional forums to further medical knowledge.

In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be made available on the DBS website and participants will be notified at the conclusion of the study in regards to their publication on the website.

17 Complaints and compensation

If you suffer any injuries or complications as a result of this study, you should contact the nurse at NSW Sexual Health Infolink (the "clinical contact" – details provided in section 20 below) as soon as possible, who will assist you in arranging appropriate medical treatment.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is caused by study procedures, or by the negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for

your injury or complication free of charge as a public patient in any Australian public hospital.

Any person with concerns or complaints about the conduct of this study should contact the Research Office Manager at SVH HREC (the "complaints contact person" – details provided in section 20 below), or the Aboriginal Health and Medical Research Council (AH&MRC) Ethics Committee.

18 Who is organising and funding the research?

This study is being conducted by the following Principal Investigators:

- Ms Bianca Prain, Centre for Population Health, NSW Ministry of Health
- A/Prof Philip Cunningham, NSW State Reference Laboratory for HIV, St Vincent's Hospital Sydney
- Dr Rick Varma, Sydney Sexual Health Centre, South Eastern Sydney Local Health District

The study is being funded by the NSW Ministry of Health.

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

No conflicts of interest are declared among the Principal and Associate Investigators in association with this study.

19 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 St Vincent's Hospital, Darlinghurst NSW (HREC Reference Number: HREC/15/SVH/400), the Aboriginal Health and Medical Research Council (AH&MRC) of NSW Ethics Committee and the NSW Corrective Services Ethics Committee.

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.

20 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information about this project or if you have any medical problems which may be related to your involvement in the study (for example, any side effects) please contact:

Clinical contact person

Name	Dr Rick Varma
Position	Director, Sydney Sexual Health Centre
Telephone	02 93827476
Email	Rick.Varma@health.nsw.gov.au

For inquiries relating to the study, the details of the study representative are:

Study contact person

Name	Mr Nigel Carrington
Position	DBS Study Coordinator
Telephone	0409 382 966
Email	nigel.carrington@health.nsw.gov.au

If you have any complaints about the way the study is being conducted or any questions about being a research participant in general, then you may contact:

Complaints contact person (Corrective Services approving this research)

Reviewing HREC	Attn: The Secretary Corrective Services Ethics Committee
Telephone	02 8346 1254
Email	ethics.committee.csnsw@justice.nsw.gov.au

Complaints contact person (AH&MRC approving this research)

Reviewing HREC	Attn: The Ethics Officer AH&MRC Ethics Committee
Telephone	02 9212 4777
Email	ethics@ahmrc.org.au

Complaints contact person (HREC approving this research)

Reviewing HREC	Attn: Research Office Manager St Vincent's Hospital Sydney HREC
Telephone	02 8382 4960
Email	SVHS.Research@svha.org.au

Informed Consent

This hepatitis C and HIV DBS test is being offered as part of a clinical trial. We need your consent to participate, to be tested and to receive results. Without your consent we cannot offer the hepatitis C and HIV DBS test to you. Please read the following statements and tick the box below if you agree.

- I acknowledge that a copy of the Information and Consent Form is available to read and download from this website (or has been provided to me).
- I have read and understood the Information and Consent form, which explains the aims of the study, the nature and the possible risks of the research.
- I agree to take part in the study described in the Information and Consent form.
- I consent to provide my information for the purposes of data collection and analysis.
- I understand that research data gathered from the results of the study may be published, provided that I cannot be identified.
- I understand that if I have any questions relating to my participation in this research, I may contact the DBS coordinator by telephone on 0409 382 966, who will be happy to answer them.
- I understand that I can withdraw from the study at any time without prejudice to any relationships I might have with staff associated with the study.
- I understand the nature of the test/procedure being performed and any risks that may be involved. I understand that I can ask further questions before undertaking this procedure and have had the opportunity to do so. I understand that I can withdraw my consent at any time.
- I understand that I will be provided results by a qualified clinician and will be supported to access further care and treatment if my result is positive.

❑ I provide my independent, informed consent to take part in the study described above, including consent to have a HIV or hepatitis C DBS test and to be contacted for results and my feedback on the service.

❑ I consent to the collection of a venous blood sample from my arm.

Name: _____

Signature:_____ Date:_____

Withdrawal of Participation – Adult providing own consent

Declaration by Participant

☐ I wish to withdraw from the NSW DBS HIV and Hepatitis C Testing Pilot Program including any sub-study and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with organisations involved in the program.

☐ I understand the implications of withdrawing from the program, as stated in the Information and Consent Form. (In the event that outstanding questions arose) Any questions I had regarding my withdrawal have been addressed by the Study Contact.

Name of Participant _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances.

Declaration by Study Contact

Name of Participant _____

The participant has withdrawn from the study due to the following circumstances:

☐ I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood the explanation.

Name of Study Contact _____