[Insert header/logo]

Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

HEPATITIS C TESTING USING POINT-OF-CARE

[Insert site name]

Title	A multi-centre, practice-level, stepped wedge cluster randomized controlled trial to compare point-of-care HCV RNA testing, dried blood spot testing, and standard of care to enhance treatment uptake among people with HCV who have recently injected drugs attending needle and syringe programs: the TEMPO study
Short Title	TEMPO Study
Protocol Number	VHCRP1904
Project Sponsor	UNSW Sydney
Coordinating Principal Investigator	Professor Jason Grebely
Site Principal Investigator	*[Site Principal Investigator name]*
Location	*[Location]*

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. The research project is looking at new ways to test and treat Hepatitis C virus infection at Needle and Syringe Programs (NSP). You're being invited to participate because you're 18 years or older, you've attended this NSP and have reported recently injecting drugs.

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

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary and there will be no cost to you. If you don't wish to take part, you don't have to. You should feel under no obligation to participate in this study. Choosing not to take part in this study will not affect your current and future medical care in any way. You will receive the best possible care whether or not you take part.

Your withdrawal from the study

You are under no obligation to continue with the research study. You may change your mind at any time about participating in the research. People withdraw from studies for various reasons and you do not need to provide a reason. You can withdraw from the study at any time by completing and signing the 'Form for Withdrawal of Participation'. This form is provided at the end of this document, and is to be completed by you and supplied to the research team if you choose to withdraw at a later date. If you withdraw from the study, you will be able to choose whether the study will destroy or retain the MBS/PBS information it has collected about you. You should only choose one of these options. Where both boxes are ticked in error or neither box is ticked, the study will destroy all information it has collected about you.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read
• Consent to take part in the research project
• Consent to have the tests and treatments that are described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

The purpose of this study is to compare three methods of testing for hepatitis C virus (HCV) infection at Australian NSPs in people who inject drugs. Two of these methods are new and one is the current testing method (called the standard of care). Routinely hepatitis C is tested by collecting a blood sample from your vein and sent to a laboratory. It is hoped that these new methods of testing for hepatitis C, which don't involve getting blood from a vein, might help more people get tested for hepatitis C and might help more people get treated. The three groups of hepatitis C testing methods being used in this study are: 1) The current testing method for HCV at the NSP (standard of care), 2) HCV testing using dried blood spots (DBS) and 3) HCV testing using a new finger stick point of care test. Methods 2 and 3 of testing for hepatitis C are not currently used or approved for routine hepatitis C testing (i.e. experimental) and are being offered here as part of this research study.

You are invited to participate in the finger-stick point-of-care group. In this group, people will be tested for HCV with a new finger-stick point-of-care (i.e. in the clinic) test. This device examines blood collected from a finger-stick (like those used by diabetics) to detect if the HCV is present and can produce results in the same day. The device was recently registered with the Therapeutics Good Administration (TGA) for the detection of HCV.

If the test shows that you have hepatitis C, the nurse will discuss treatment with you. If you are suitable and willing to have treatment for your hepatitis C, you will be prescribed treatment through the Pharmaceutical Benefits Scheme (PBS) which is the government subsidised treatment scheme. You will continue to be supported through treatment by the site study team at the NSP.

The study will look at the proportion of HCV detected people who start treatment 12 weeks after being tested for HCV.

This research has been initiated by the principal researcher, Professor Jason Grebely of UNSW. This study is sponsored by the Kirby Institute at the UNSW Sydney in Sydney, Australia. This research has been funded by the National Health and Medical Research Council with support from the research partners (see section 19).

3 What does participation in this research involve?

If you agree to participate in this project, you will be asked to sign the Participant Consent Form prior to any study assessments being performed. This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

This study will be conducted at least over 3 years, and your participation would be for a maximum of 1 year.

Below is an outline of the clinic visits you would be required to attend, and what would happen at the visits, if you decide to participate in this study. There are three phases to the study: Screening, Treatment and Follow-Up. Only participants who have hepatitis C will attend the treatment and follow-up phase.

If you agree to take part in this study, there is an additional optional component which you may choose to participate in. The optional component of the study is the linkage of routinely collected information about you to look at your liver-related health and long-term outcomes.

You can participate in the study without the linkage of your information. Additional information on the optional component of the study is provided in section 18.

Below is an outline of the visits and assessments you will be required to complete.

SCREENING VISIT – ALL PARTICIPANTS (REQUIRED)

- **Demographics**

You will be asked some general questions that describe you such as your age, gender and nationality.

- **Complete questionnaires**

You will be asked to complete questionnaires about your background including whether you are of Aboriginal and/or Torres Strait Islander origin, your level of education, your income and whether you have previously been in jail or juvenile justice. Social factors such as these have been shown to be associated with hepatitis C and treatment response.

You will also be asked about any current or past alcohol and drug usage, drug treatment history, injecting risks behaviours including sharing needles with partners and equipment sharing, previous hepatitis C testing and treatment, you experience with overdose and naloxone, your experience with hospital admissions and police, your attendance and use of services at the NSP, and about the way you feel physically, and your current mood. **All of your answers are completely confidential and will not be used for any other purpose than as information for the study.**

It is expected that these questionnaires will take 30 to 40 minutes to complete at the screening visit and 20 to 30 minutes for subsequent visits.

- **Test for hepatitis C using blood from a finger-stick and a point-of-care device**

A small amount of blood will be collected (less than a teaspoon) using a finger-stick (same procedure as used for blood sugar testing in diabetics) for a device to test the amount of HCV found in your blood (a viral load). The results of this will be available to you on the same day.

The results from the laboratory tests may be shared with state health authorities.

- **Collect research samples via a finger-stick (dried blood spot)**

A small amount of blood will be collected (less than a teaspoon) using a finger-stick (same procedure as used for blood sugar testing in diabetics). Five drops of blood will be collected onto a collection card. At the end of the study, these samples will be tested using commercial laboratory tests for hepatitis C to confirm the type of HCV (if any) is present. These results will not be available to you or the site study team.

For most people, only 1 finger-prick is required for the blood collection. For some people, 2 finger-pricks may be required for the blood collection for both the point-of-care device and the research sample.

Your contact details will be collected. These contact details will only be used to contact you about your results and send reminder messages for study visits. The name and phone number and/or email address of up to three secondary contacts will be collected in case we cannot reach you directly.

If you do not have hepatitis C, you will not need to attend any further study visits.

If you are found to have hepatitis C, you will be asked to attend additional study visits – these are outlined below.

TREATMENT – HEPATITIS C POSITIVE ONLY (OPTIONAL)

If you are found to have hepatitis C and the nurse assesses you to be eligible for treatment and you would like to start treatment, you will be prescribed one of the approved oral hepatitis C

treatment medications. The nurse will discuss the treatment options with you and together with the doctor will decide which is the best treatment option for you. Treatment will either be three tablets once per day for 8 weeks or one tablet once per day for 12 weeks.

It is up to you whether you agree to start treatment. If you do and are eligible for treatment, treatment will be prescribed through the Pharmaceutical Benefits Scheme (PBS) as part of standard of care.

Before and/or during treatment the site study team may recommend additional tests and visits. These tests and/or visits are the same as what you would receive if you did not participate in the study.

You will also have tests for HIV and hepatitis B (HBV) before starting treatment. These tests will be done using fingerstick point-of-care tests. The point-of-care tests use finger-stick blood samples (3 drops for each virus tested) for HIV and HBV. The HIV point-of-care test (Alere HIV Combo) is currently approved for use in Australia. The HBV point-of-care test (Determine ™ HBsAg) is currently not approved for use in Australia. These would only be performed as part of this research study. If these point-of-care tests are positive you will have a standard blood test to confirm the positive HIV or HBV result.

You will receive follow-up counselling and medical advice for these tests. If you are concerned about these tests or the results, speak to the study staff about this. The study staff can provide you medical advice on these tests and offer counselling support or link you with support services available in your state or territory.

If your test results are positive/detected for these tests, the study doctors may be required by state/territory law to notify government health authorities. Signing the consent form means that you agree to have this testing; it will not be done without your consent.

FOLLOW-UP VISITS - HEPATITIS C POSITIVE ONLY (REQUIRED)

You will be asked to return to the NSP at 12 weeks (i.e. 3 months), 24 weeks (6 months) and 52 weeks (12 months) for follow-up visits.

At the follow up visits you will have the following procedures:

- **Complete questionnaires**

You will be asked to complete similar questionnaires to the ones previously completed at the screening visit.

- **Test for hepatitis C using blood from a finger-stick/point-of-care device**

A small amount of blood will be collected (less than a teaspoon) using a finger-stick (same procedure as used for blood sugar testing in diabetics) for a device to test the amount of HCV found in your blood (a viral load). The results of this will be available to you on the same day.

If the on-treatment visits coincide with the follow-up visits, you may complete all the activities in the same visit.

The results from the laboratory tests may be shared with state health authorities.

Your contact details will be collected. These contact details will only be used to contact you about your results and send reminder messages for study visits.

ADDITIONAL COSTS AND REIMBURSEMENT

There are no costs associated with participating in this research project. Participation in this study will not cost you anything and you will not be paid for participating. You will be reimbursed $30 per visit for your time for study visits that involve assessments and/or blood collection: Screening and, if applicable to you, 12-week follow-up visit, 24-week follow-up visit and 52-week follow-up visit. This means that participants who are HCV negative will receive a maximum of $30 for their

time at the Screening visit while those who are HCV positive and return for follow-up visits will receive a maximum of $120.

If you start treatment for hepatitis C, the study will pay for the dispensing fees for the medication at the local pharmacy.

4 What do I have to do?

If you decide to be in this study, there are certain things you must do before, during, and after the study period.

Some are listed below, but there could be others that the site study team will discuss with you:

- You must be able to provide written consent to be in this study.
- If required, you must be available to attend the follow-up visits in the study
- You must tell the site study team if you think you might be pregnant, you are pregnant, or you are breastfeeding.

If you wish to commence treatment:

- You must tell the site study team about all medications or supplements you are taking including those you take as needed or which you take only occasionally. This is to make sure there is no interaction between the hepatitis c treatment and the medication and supplements you are taking.
- You must ask your site study team before you take any new medications during the study.
- If you decide to take part in this study, it is very important that you attend all visits as scheduled, including the follow-up visit.
- Only you should take the hepatitis C medication. They must be kept out of the reach of children. Please also keep the medication away from people who may not be able to read or understand the label.
- You should take the medication every day at the regularly scheduled time with or without food.
- You must follow all instructions given to you while you are participating in this study. If you do not, you may be removed from the study. If you are unsure about what you are supposed to do, ask the site study team.
- You must not be pregnant or become pregnant during this study (women of child bearing potential only).

If you cannot follow these restrictions, you should not be in this study.

5 Other relevant information about the research project

This research project involves several NSPs across Australia. We expect to recruit approximately 3,300 people for hepatitis C testing throughout Australia of which we expect around 660 will have hepatitis C. NSPs will be randomly assigned to complete testing for hepatitis C using dried blood spots, a point-of-care test or by the standard of care test.

6 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.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with any of the participating Institutions.

7 What are the alternatives to participation?

You do not have to join this study to have hepatitis C testing or treatment. You can have hepatitis C testing and treatment as part of standard of care. Standard hepatitis C testing is done by taking a blood sample from a vein and sending it to a laboratory for testing. The results usually take about a week to come back. The site study team will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. You will have a hepatitis C test. If you do have hepatitis C infection and decide to commence treatment as part of this study there is no guarantee that your infection will be cured. It is possible that your condition may remain unchanged or could worsen during your participation in the study. However, your participation may provide valuable information to improve the management of people who inject drugs who are infected with hepatitis C in the future.

You will not be provided with hepatitis C treatment medication once the study has concluded and you may be limited from participating in future studies related to the medication or other future hepatitis C treatment studies.

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

If you choose to take part in this study, the main risks and disadvantage in taking part are below.

- **Finger-prick**

The collection of blood via the finger-prick method may be uncomfortable, but rarely results in any significant problems. The site of the piercing may be tender following the procedure.

- **Research tests for HCV, HIV and/or HBV**

The point-of-care tests used in this study are very accurate:

- In people with HCV, the point-of-care test will be correct more than 99 times out of every 100 tests.
- In people with HIV, the point-of care test will be correct more than 99 times out of every 100 tests.
- In people with HBV, the point-of care test will be correct more than 97 times out of every 100 tests.

In a very small number of cases for these tests there can be a:

1. “False negative”: this means that the test does not detect the virus in a person’s blood sample when the person does have the virus. There is a risk that you could transmit the virus to others and miss out on the opportunity to have your virus infection treated, which may cause you health problems in the future. It is recommended that people who inject drugs have regular HCV, HBV and HIV tests and always use clean injecting equipment for every injection.
2. “False positive”: this means that the test detected virus in a person’s blood sample, but the person does not have the virus. There is a risk that you could start hepatitis C treatment when in fact you don’t have hepatitis C. The risk to you if that happens are the side effects of the treatment which are generally mild and resolve after treatment is finished. Common side effects of hepatitis C treatment are headache, tiredness, nausea depending on which treatment you were given and how you respond to treatment. Not everyone who takes hepatitis C treatment has side effects. If your HIV or HBV test is positive, you would have a confirmatory test before starting any medication.

In both cases, if you believe you may be in this situation, speak to the study clinician. Your clinician can do another type of hepatitis C test, which involves drawing blood from you vein to check the results of finger-prick test.

If you are found to be HCV positive, the study clinician will discuss with you whether you wish to start treatment through standard of care. This would likely involve additional procedures as part of standard of care work-up for HCV treatment. The risks and disadvantages of the treatment

work-up and treatment itself will be discussed with you by the study clinician and are no different than if you had chosen not to participate in this study.

10 What will happen to my test samples?

The blood samples collected for this study are mandatory for this research. You will have blood samples taken during the study to monitor your health and HCV in your blood. Any remaining blood samples will be sent to the Viral Hepatitis Clinical Research Program (VHCRP) Research Laboratory, UNSW Sydney, which is part of the Kirby Institute's laboratories, for testing of the amount of virus in your blood and to study factors that may influence viral clearance, such as genes that influence your immune system, variations in the HCV that might make the virus more susceptible or resistant to treatment. These virus variations might also be used to look at transmission of the HCV.

Your research samples will only be identified with a unique study identification number, initials and your date of birth. The VHCRP Research Laboratory, UNSW Sydney will not have access to your name or other personal details and will not be able to link the sample to you personally. These tests will be done at the end of the study for research purposes and you will not receive the results.

Any remaining research samples will be stored for use in future hepatitis C related research until all of the samples have been used up or until the samples are no longer viable. Not all potentially beneficial future research can be known at any one time, as the need for future research is determined by ongoing developments in the field. Your samples and/or data may be provided to other researchers for future research provided it is ethically approved. Any future research projects using these samples will be reviewed and approved by the Human Research Ethics Committee prior to commencement. Having your samples stored for future research is optional. You do not have to agree to this if you don't want to. If you do not want your samples stored for future research, please tick the 'opt out' box on the consent form at the end of this document.

There is the possibility of this research resulting in commercially viable technology or treatments. However, you will not be able to claim financial benefit from any discoveries arising from the use of your blood sample. Your samples and data will not be sold.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your site study team will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your site study team and doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your site study team might consider it to be in your best interests to withdraw you from the research project. If this happens, they will explain the reasons and arrange for your regular health care to continue.

12 Can I have other treatments during this research project?

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your site study team and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your site study team about any changes to these during your participation in the research project. Your site study team should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

13 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the site study team and relevant study staff will not collect additional personal information from you, although personal deidentified information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

14 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons such as decisions made by the Sponsor or by local regulatory/health authorities.

15 What happens when the research project ends?

You will receive your normal, routine medical care both during and after the study is completed.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the consent form, you consent to the site study team and relevant research staff collecting and using personal information about you and your study data for this research project but also future related research on hepatitis C. Any information obtained in connection with this research project that can identify you will remain confidential.

When you are enrolled in the study, you will be given a unique study identification number and a 4-letter code based on a combination of your first and last name. Information and research samples from this study will be labelled with the unique study number, the 4-letter code and your date of birth. Your name will never be used to identify any data or research samples.

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.

After the completion of the research project, your study data may be used in future hepatitis related research. Not all potentially beneficial future research can be known at any one time, as the need for future research is determined by ongoing developments in the field. Any future research projects using these samples will be reviewed and approved by the Human Research Ethics Committee prior to commencement.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form, you agree to the study team accessing health records if they are relevant to your participation in this research project.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor, UNSW Sydney, the institution relevant to this Participant Information Sheet, *[Name of institution],* or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

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 permission. Only your unique study number will be used to ensure your confidentiality.

Information about your participation in this research project may be recorded in your health records.

Any information obtained for the purpose of this research project and for the future research described in Section 16 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.

17 Complaints and compensation

If you suffer any injuries or complications as a result of this study, you should contact the site study team as soon as possible and you will be assisted in arranging appropriate medical treatment. In the event of loss or injury, the parties involved in this research project have agreed that 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 sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in the study (for example, the researcher, the hospital, or the treating doctor). 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. You do not give up any legal rights to compensation by participating in this study. 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.

18 OPTIONAL – Linkage of your data to health databases

The second part of this study is data linkage which involves the researchers accessing your records held in several standard databases to look at your liver-related health and long-term outcomes.

There are two types of data linkage we would like to do as part of this study. Both are optional. You do not have to agree to data linkage if you don't want to.

18.1 Health and Imprisonment data linkage:

The researchers would like to link the data collected about you in the study to information about your health, medications, treatments and imprisonment including:

- hepatitis B and C diagnosis;
- HIV/AIDS diagnosis;
- cancer diagnosis;
- hospital admissions, emergency departments and ambulance use;
- mental health service use;
- drug dependence treatment (e.g. OST);
- registry of births, deaths, and marriages records;
- imprisonments

If you agree to the Health and Imprisonment data linkage your first name, last name, date of birth, sex, full address and postcode will be recorded by the researchers and will be stored by the independent Data Custodian at The Kirby Institute. No one but the Data Custodian and the Clinical Trials Manager at the Kirby Institute will have access to this information. The Data Custodian will send these details securely to the organisations who conduct the confidential data linkage (e.g. the Centre for Health Record Linkage, www.cherel.org.au, and the Australian Institute of Health and Welfare, www.aihw.gov.au). Any information used from these data sources will be treated completely confidentially and used for the purposes of the research only.

If you do not want to participate in this part of the study you can opt out on the consent form.

Approval from the NSW Population and Health Services Research Ethics Committee (PHSREC) and all required Human Research Ethics Committees will be sought prior to any data linkage being performed.

18.2 Medicare Benefits Schedule/Pharmaceutical Benefits Scheme (MBS/PBS) data linkage:

The researchers would like to link the data collected about you in the TEMPO study to information about your prescription medicines you have filled at pharmacies (PBS), and your doctor visits and the associated costs (MBS) from the following sources:

- Medicare Benefits Schedule (MBS) records;
- Pharmaceutical Benefits Scheme (PBS) records;

To participate in this you will be asked to fill out and sign the MBS and/or PBS consent form which is a separate form, authorising the study access to your complete MBS and/or PBS data as outlined on the back of the consent form. The MBS/PBS consent form records your first name, last name, date of birth, sex, Medicare card number and full address.

The MBS and/or PBS data will only be used for the purposes outlined in this participant information and consent form and study protocol. The MBS and/or PBS consent form will be stored securely by the independent Data Custodian at The Kirby Institute. No one but the Data Custodian and the Clinical Trials Manager at the Kirby Institute will have access to this information. The Data Custodian will send your MBS and/or PBS consent form securely to the Services Australia who holds this information confidentially.

18.3 What are the possible risks and disadvantages of taking part in the data linkage studies?

This study aims to improve future treatment of liver disease and hepatitis C infection. It is possible that you may receive no other benefit from participating in the data linkage aspects of the study, but you may help future patients by providing important information about the long term outcomes of people assessed for hepatitis C.

There is a small risk to your privacy because personal information is used in the record linkage process. This risk is minimised by separating the processes of record linkage and data analysis. The record linkage only uses personal information such as name, date of birth, and address and not health information. The research team will not have access to any of your personal details; at the time of linkage a unique personal identification number will replace your personal information. The data provided to the researchers contains personal identification numbers and health information but no names, dates of birth or addresses. All safety measures have been put in place to ensure that the confidentiality of the participant's information is maintained, including removal of identifying information, the use of unique study numbers and adherence to strict guidelines regarding data transfer, storage and access. When the study is complete, your identifiable data will be securely destroyed.

18.4 Storage, retention and destruction of your information

Strict measures are in place to ensure data security is always complied. Encrypted information received by the research team will be stored in a secure network protected by a firewall and individual files will be password protected. Files including electronic linked information will be restricted and only accessible by authorised research staff. Files including electronic linked information will not be stored in any other format or location other than those approved by data custodians and the St Vincent's Hospital Human Research Ethics Committee. Your MBS and/or

PBS consent form containing your confidential information will be stored in a secure area only accessible to the Data Custodian and Clinical Trials Manager.

All data will be kept for a minimum of 15 years from the end of the study as per regulatory requirements for clinical trials, after which electronic data and MBS and/or PBS consent forms will be disposed of in a secure and safe manner in accordance with the UNSW Recordkeeping policy and by paper shredding, accordingly.

19 Who is organising and funding the research?

This study is sponsored by the Kirby Institute at the UNSW Sydney. This research has been initiated by Prof Jason Grebely and medication will be accessed through the PBS. This is a partnership study which has received funding from the National Health and Medical Research Council (NHMRC) and Gilead. Equipment is being provided in-kind by Cepheid and Hologic. The study is also conducted with the support from state health services and state/national community organisations which support people with hepatitis and/or people who inject drugs.

20 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 Hospital2019/ETH13041 and the Aboriginal Health & Medical Research Council of NSW 1587/19.

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.

21 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 concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study investigator on *[Insert phone number]* or any of the following people:

Clinical contact person

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

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

Reviewing HREC name	St Vincent's Hospital HREC
HREC Executive Officer	Research Officer
Telephone	02 8382 4960
Email	SVHS.Research@svha.org.au

Reviewing HREC name	Aboriginal Health & Medical Research Council Ethics Committee
HREC Executive Officer	Chairperson
Telephone	02 9212 4777
Email	ethics@ahmrc.org.au

If you have a privacy complaint in relation to the use of your MBS/PBS data you should contact the Office of the Australian Information Commissioner. You will be able to lodge a complaint with them.

Website: www.oaic.gov.au
Telephone: 1300 363 992
Email: enquiries@oaic.gov.au
Mail: GPO Box 5218, Sydney NSW 2001

[Insert header/logo]

Consent Form - *Adult providing own consent*

Title	A multi-centre, practice-level, stepped wedge cluster randomized controlled trial to compare point-of-care HCV RNA testing, dried blood spot testing, and standard of care to enhance treatment uptake among people with HCV who have recently injected drugs attending needle and syringe programs: the TEMPO study
Short Title	TEMPO Study
Protocol Number	VHCRP1904
Project Sponsor	UNSW Sydney
Coordinating Principal Investigator	Professor Jason Grebely
Site Principal Investigator	*[Site Principal Investigator name]*
Location	*[Location]*

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *[Name of Institution]* concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

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 project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I consent to the storage and use of study data and remaining blood samples taken from me for use, as described in this information sheet for:

- This specific research project and
- Other research that is closely related to this research project and
- Any future hepatitis C related research (if you do not agree, tick the box below)

☐ I do not consent to my samples being stored for future research.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

I understand that I will be given a signed copy of this document to keep.

I understand there is an optional component in the study of use of my personal details for data linkage and by indicating the below do not consent to participate in this component:

☐ I **do not** wish to provide my personal details for use in the Health and Imprisonment data linkage study.

☐ I **do not** wish to provide my personal details for use in the MBS/PBS data linkage. (Note: MBS/PBS data linkage is on a separate consent form)

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Investigator/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Investigator/ Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

[Insert header/logo]

Form for Withdrawal of Participation - *Adult providing own consent*

Title	A multi-centre, practice-level, stepped wedge cluster randomized controlled trial to compare point-of-care HCV RNA testing, dried blood spot testing, and standard of care to enhance treatment uptake among people with HCV who have recently injected drugs attending needle and syringe programs: the TEMPO study
Short Title	TEMPO Study
Protocol Number	VHCRP1904
Project Sponsor	UNSW Sydney
Coordinating Principal Investigator	Professor Jason Grebely
Site Principal Investigator	*[Site Principal Investigator name]*
Location	*[Location]*

Declaration by Participant

Please tick the applicable box/boxes for each component of the research project you wish to withdraw from.

☐ I wish to withdraw from participation in the TEMPO research project

☐ I wish to withdraw from participation in future health and imprisonment linkage studies.

☐ I wish to withdraw my consent to the storage and use of my remaining samples for future hepatitis C related research.

MBS and PBS Data Linkage:

☐ I wish to withdraw from participation in future MBS and PBS record linkage studies.

*If the above box is selected, please choose **one** option below:*

☐ DESTROY all MBS and PBS health information collected about me to date so it can no longer be used for research, or

☐ RETAIN all MBS and PBS health information collected about me to date so it can continue to be used for research.

I understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with *[Institution]*.

I understand that:

1. no further information about me will be collected for the study from the withdrawal date;
2. information about me that has already been analysed and/or included in a publication by the study, may not be able to be destroyed; and
3. choosing to withdraw from the study will not affect my access to Health Services or Government benefits.

Name of Participant (please print) _____

Signature _____ Date _____

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 below.

Declaration by Study Investigator/Senior Researcher†

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

Name of Study Investigator/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.