**Participant Information Sheet/Consent Form**

**Interventional Study** -*Adult providing own consent*

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| --- | --- |
| **Title** | Point Of Care Hepatitis C testing and subsequent treatment uptake in Addiction Medicine residential withdrawal unit (POCAM): a pilot study |
| **Short Title** | POCAM |
| **Protocol Number** | v1.10 |
| **Project Sponsor** | Gastroenterology Department, St Vincent’s Hospital Melbourne |
| **Coordinating Principal Investigator** | Prof Alex Thompson MBBS PhD FRACP St Vincent’s Hospital, Melbourne |
| **Chief Investigators** | A/Prof Jacinta Holmes MBBS PhD FRACP St Vincent’s Hospital Melbourne  A/Prof Yvonne Bonomo MBBS PhD FRACP FAChAM  Dr James Williams MBBS St Vincent’s Hospital Melbourne |
| **Location** | Depaul House, St Vincent’s Hospital Melbourne |

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this study. This is because you have a history of substance use and therefore at risk of getting hepatitis C virus (“hep C”), a virus which affects your liver. The research project is trialling a new rapid point-of-care test for hep C and immediate commencement of hep C treatment. The new test is called the Cepheid Xpert HCV VL Fingerstick test. It tests for the hep C virus using a small sample of blood collected from a prick on your finger. It takes a little over an hour to get the test result which tells us how much virus is in your system.

This Participant Information Sheet/Consent Form tells you about the study. It explains the tests, treatments and study visits 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. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the study, 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 investigate whether offering clients same-day hep C testing, results and potentially treatment during their stay at Depaul House is an effective and acceptable way to diagnose hep C and link people with hep C care. This will be in comparison to the usual way of testing for hep C which involves taking a blood sample from a vein. We want to see if rapid hep C diagnosis results in more people starting hep C treatment and whether people prefer this new way of getting a hep C test.

Currently, the usual way for hep C testing requires a blood sample taken from a vein to be sent to a laboratory to be processed. The test result is sent to the healthcare provider and the patient receives their result at another appointment, usually at least a week later. A patient with hep C may need further clinical assessment before being started on hep C treatment. This process involves many steps and can be difficult for patients.

With this study, the Investigators want to see if people find a same-day (rapid) blood test result acceptable, and if they are more likely to get tested and start hep C treatment than the usual way. The results of this study may contribute to changes in how hep C testing is offered to people in the future.

Medications, drugs and devices have to be approved for use by the Australian Federal Government. The Cepheid Xpert HCV VL Fingerstick test (rapid test) has recently been approved by the Therapeutics Goods Administration (TGA) in Australia for the purpose of hep C diagnosis.

This research has been initiated by Professor Alex Thompson. This research is being conducted by St Vincent’s Hospital Melbourne. It is funded by the Gastroenterology and Addiction Medicine Departments at St Vincent’s Hospital Melbourne.

**3 What does participation in this research involve?**

To be eligible to participate in this research, you need to:

* Be at least 18 years old,
* Admitted to Depaul House during the recruitment phase of the study
* Be able to provide written informed consent,
* Consent to multiple visits and to completion of questionnaires,
* Not currently engaged in care for treatment of hepatitis C infection, hepatitis B or HIV,
* Fulfill the standard criteria for HCV diagnosis to initiate treatment

You would not be eligible if you are/have:

* Pregnant or breastfeeding at time of commencement of hep C medications;
* Clinical evidence of decompensated cirrhosis;
* Diagnosed and/or undergoing treatment for hepatocellular carcinoma;
* Awaiting liver transplantation;
* Currently engaged in care for treatment of hepatitis C infection, hepatitis B infection or HIV;
* Unable or unwilling to present to pick up ongoing hep C medication supply for treatment (four weekly basis);
* Receiving medications which are contra-indicated to co-administration of hep C medication or at risk of significant drug-drug interactions;
* Evidence of any condition, therapy, laboratory abnormality or other circumstance (current or prior) that may confound the study’s results, or interfere with participation for the full duration of the study, such that it is not in the best interest of the participant.

If you decide to participate in this research you will be offered hep C testing using the new *point-of-care rapid test* with the possibility of same-day hep C treatment commencement.

Once you have heard all about the study, asked any questions you have, and signed your consent to participate, you will complete hep C testing (through a fingerprick sample for rapid testing) and a clinical assessment for hep C treatment. During your admission you will undergo liver assessment with a blood test and FibroScan. This is an ultrasound of your liver to see if there is scarring (a common complication of hep C infection, called ‘cirrhosis’). All participants can be offered hep C treatment and clinical care, regardless of whether scarring is present or not.

The result of fingerprick hep C test will take up to an hour to come back. If the test shows you have hep C, you will be offered treatment with hep C medication for 8-12 weeks. You will be asked to return for further clinic appointments for review and completion of questionnaires. The schedule for study visits is:

* Study attendance 1 (Depaul House admission): hep C testing, hep C treatment assessment including FibroScan, questionnaire. You may start hep C treatment during attendance 1.
* Study attendance 2 (optional): week 4 of treatment review and questionnaire
* Study attendance 3 (optional): week 8 of treatment review and questionnaire (if treatment is longer than 8 weeks)
* Study attendance 4: end of treatment blood test to see if the virus has gone and questionnaire
* Study attendance 5: blood test to see if the hep C has stayed away at least 4 weeks after treatment completion

This will take 12-16 weeks, depending on the length of your hep C treatment course.

To help us determine if you have commenced your hep C treatment, we may also contact the Pharmaceutical Benefits Scheme (PBS) using your name, date of birth and Medicare number, to ask if your script has been filled.

At study attendance 1, you will also be offered testing for other blood borne viruses, including hepatitis B and HIV. You can choose not to participate in this.

If post commencement of treatment you wish to continue the study from a different location, this will also be possible. Further hep C treatment required and blood tests will be organised by our study team, which with your consent, may be done in conjunction with a nominated health practitioner at the different site. We may also call you to complete required questionnaires over the phone.

Overall, the study will take around 12 months to recruit participants and follow participants up for clinical review and post-treatment outcomes.

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.

There are no additional costs associated with participating in this research project. All tests, medication, and medical care required as part of the research project will be provided to you free of charge. However, you may be charged a small dispensing fee by the pharmacist to collect your medications.

It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

**4 What do I have to do?**

To participate in this study, we require you to:

* undergo hep C testing using the new, rapid fingerstick blood test;
* complete study questionnaires;
* consider starting hep C treatment if you have hep C;
* attend addiction medicine outpatient clinic for further clinical review and questionnaire completion if you commence hep C treatment;
* complete blood tests at assigned time points according to your own treatment regime.

You cannot participate in this study if you fill any of the exclusion criteria listed above in section 3.

**5 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 or not to take part, or to take part and then withdraw, will not affect your routine care or your relationship with Depaul House or St Vincent’s Hospital Melbourne.

**6 What are the alternatives to participation?**

You do not have to take part in this study to receive hep C testing and treatment Depaul House or St Vincent’s Hospital. You can still receive testing and treatment through Depaul House without taking part in this study. Your study doctor 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.

**7 What are the possible benefits of taking part?**

We cannot guarantee that you will receive any benefits from this research; however, possible benefits may include receiving a prompt (same-day) result on your hepatitis C test result, and the opportunity to commence hep C treatment on the same day as your hep C test, or at a time soon after that suits you.

The greatest benefit for all participants is the opportunity to start hepatitis C treatment and stop the formation of scar tissue in the liver if you are found to have hep C. You will be involved with a team of doctors and nurses who want to improve the health of people living with hep C.

If we find that the rapid point-of-care test is acceptable to participants and feasible to use in this setting, then these results may contribute to changing practice for hep C testing. The test may become available to other people at risk of hep C in the future.

**8 What are the possible risks and disadvantages of taking part?**

There are only minor risks when a blood sample is collected. For example, at the site where the blood is taken, there is a chance of pain, bleeding and /or bruising, and a very small risk of infection and /or inflammation of the vein (phlebitis). If this happens it can be easily treated.

Medical treatments sometimes cause side effects. The hep C treatments may have side effects such as symptoms of nausea, vomiting and diarrhoea, or fatigue and headaches.

You may have none, some, or all, of these effects, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects. In general, all direct acting antivirals for hepatitis C are very safe and have very few side effects.

If you do get side effects, you can call us to discuss this. A member of the study team will be able to provide you with advice over the phone or tell you where you can get further medical care. Some of the Hepatitis C medications may interact with other medications. If you are going to start new medications while on treatment, we need to check first that it is safe to take them at the same time.

Sometimes when completing questionnaires or discussing more sensitive topics, you might become upset about what is discussed. If this occurs, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support can also be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

While we are very careful to keep your personal information confidential, there are limits to that confidentiality. You should not tell us anything specific about illegal behaviours that you have not been charged with or have not been dealt with by a court. Please don’t reveal things like names, dates or places. We cannot guarantee the confidentiality of such information.

Please be aware that, while we will keep your information completely confidential in most instances, there are some situations where we would have to disclose things you have told us. They are if:

* We think you are going to seriously harm yourself;
* We think you are going to seriously harm someone else;
* We have been required to by police or a court of law.

If this were the case, the information could potentially be used against you in legal proceedings. To our knowledge, researchers at this institution have never been required by law to provide information about research participants. If we are ever required to do so, we would do our best to notify you before disclosing anything.

**9 What will happen to my test samples?**

Blood samples taken from a vein at each relevant study visit will be transported to St Vincent’s Pathology according to Australian National Standards. Additional blood samples will be stored at the Victorian Infectious Diseases Laboratory (VIDRL) for future hep C testing in the event that your treatment is not effective, or you get reinfected, as is the standard of care for hep C treatment management.

If a test shows you have hep C, hep B or HIV, the study team are required by 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.

**10 What if new information arises during this research project?**

During the research project, new information about the risks and benefits of the project may become known to the researchers. If this happens, you will be told about this new information and your doctor will discuss whether this new information affects you.

**11 Can I have other treatments during this research project?**

You can start tablets for other health issues during the study. However, because some other medications can potentially interact with the hepatitis C drugs, you must first tell us so that we can check that it is safe that both medications are taken at the same time. You should also tell your study doctor about any changes to your usual medications during your participation in the research project.

**12 What if I withdraw from this research project?**

If you decide you want to withdraw from the study, you can discuss it with a member of the study team before you withdraw. That way we can work through your reasons for wanting to withdraw. Of course, it is entirely your decision to do so.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although health 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 up to the time you withdraw will form part of the research project results. You will not be identified.

**13 Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly if the testing is shown to not be helpful or perhaps worsen outcomes for participants.

**14 What happens when the research project ends?**

At the end of this study, you will be provided with some information about reducing your risk of hep C reinfection and what to do if you are concerned that you may have become reinfected. In most cases you will not need any follow up care. However, if we are concerned you have risk factors for progression of your liver disease, we will refer you to a convenient liver clinic for your ongoing care.

**Part 2 How is the research project being conducted?**

**15 What will happen to information about me?**

By signing the consent form, you consent to the study team collecting and using personal information about you for the research project. Information about you may be obtained from your health records held at this service 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.

Any information obtained in connection with this research project that can identify you will remain confidential. We will keep any contact details separate from all the other information you give us or that we get from other organisations. We will code your interviews so that only members of the research team will know who they belong to.

Your confidential information will be kept for five years following publication, in line with research requirements. It will be shared only with your permission, or if we are required to share it by law.

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. Information in any written report or presentation from this study will not identify you or anyone else. Results from this study will be available to the general public.

In accordance with relevant Australian and Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

**16 Complaints and compensation**

If you suffer any harm as a result of this research project, you should contact the study team as soon as possible. We will aid you get any help you require.

**17 Who is organising and funding the research?**

This research project is being conducted by Professor Alexander Thompson, the Head of Gastroenterology at St Vincent’s Hospital Melbourne. The research is being funded by the Gastroenterology and Addiction Medicine Departments at St Vincent’s Hospital Melbourne.

**18 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.

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.

**19 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 Dr Michael MacIsaac on (03) 9231 3580 or any of the following people:

**Clinical contact person**

|  |  |
| --- | --- |
| Name | Dr James Williams |
| Position | Addiction Medicine registrar – St Vincent’s Hospital Melbourne |
| Telephone | (03) 9231 6943 |
| Email | James.Williams3@svha.org.au |

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**

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| --- | --- |
| Position | Patient Liaison Officer at St Vincent’s Hospital Melbourne |
| Telephone | (03) 9231 1954 |
| Email | PLO@svhm.org.au |

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 Melbourne HREC |
| HREC Executive Officer | Executive officer of research |
| Telephone | (03) 9231 2394 |
| Email | research.ethics@svhm.org.au |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Consent Form -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | Point Of Care Hepatitis C testing and subsequent treatment uptake in Addiction Medicine residential withdrawal unit (POCAM): a pilot study |
| **Short Title** | POCAM |
| **Protocol Number** | v1.0 |
| **Project Sponsor** | Gastroenterology Department, St Vincent’s Hospital Melbourne |
| **Coordinating Principal Investigator/**  **Principal Investigator** | Prof Alex Thompson MBBS PhD FRACP St Vincent’s Hospital Melbourne |
| **Associate Investigator(s)** | A/Prof Jacinta Holmes MBBS PhD FRACP St Vincent’s Hospital Melbourne  A/Prof Yvonne Bonomo MBBS PhD FRACP FAChAM  Dr James Williams MBBS St Vincent’s Hospital Melbourne |
| **Location** | Depaul House, St Vincent’s Hospital Melbourne |

**Consent Agreement**

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 St Vincent’s Hospital 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 understand that I will be given a signed copy of this document to keep.

**Declaration by Participant – for participants who have read the information**

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| Name of Participant (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| Declaration - for participants unable to read the information and consent form  Witness to the informed consent process  Name (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \* Witness is not to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older. |

**Declaration by Study Doctor/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.

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|  | | | | | | |
|  | Name of Study Doctor/  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.

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 consent to the storage and use of blood and tissue samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for:

• This specific research project

• Other research that is closely related to this research project

• Any future research.

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|  | Name of Study Doctor/  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.

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

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| --- | --- |
| **Title** | Point Of Care Hepatitis C testing and subsequent treatment uptake in Addiction Medicine residential withdrawal unit (POCAM): a pilot study |
| **Short Title** | POCAM |
| **Protocol Number** | v1.9 |
| **Project Sponsor** | Gastroenterology Department, St Vincent’s Hospital Melbourne |
| **Coordinating Principal Investigator/**  **Principal Investigator** | Prof Alex Thompson MBBS PhD FRACP St Vincent’s Hospital, Melbourne |
| **Associate Investigator(s)** | A/Prof Jacinta Holmes MBBS PhD FRACP St Vincent’s Hospital Melbourne  A/Prof Yvonne Bonomo MBBS PhD FRACP FAChAM  Dr James Williams MBBS St Vincent’s Hospital Melbourne |
| **Location** | Depaul House, St Vincent’s Hospital Melbourne |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with St Vincent’s Hospital.

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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| Summary of verbal communication of withdrawal: |

**Declaration by Study Doctor/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.

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|  | | | | | | |
|  | Name of Study Doctor/  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.