

**Participant Information Sheet/Consent Form**

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

*PARTICIPANT consenting to testing for hepatitis C*

St Vincent’s Hospital - Melbourne

|  |  |
| --- | --- |
| **Title** | **C No More:** A prospective pilot study to evaluate the feasibility of hepatitis C point of care testing and treatment initiation for individuals receiving a community corrections orders. |
| **Protocol Number** | 1.3 |
| **Project Sponsor** | St Vincent’s Hospital Melbourne |
| **Principal Investigators** | Dr Rebecca Winter, Prof Alexander Thompson, A/Prof Jacinta Holmes |
| **Associate Investigator(s)** | Dr Tim Papaluca  Prof Mark Stoové  Mr Sione Crawford  Ms Jane Dicka  Dr Shelley Walker  Ms Samara Griffin (student researcher) |
| **Location** | St Vincent’s Hospital Melbourne |

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

**1 Introduction**

You are invited to take part in this research project. You are invited to participate because we believe that people who are receiving a community corrections order may have a higher likelihood of being affected by hepatitis C infection. This is because one in four people within Victorian prisons have been exposed to hepatitis C infection, a viral infection which damages your liver. There are no services set up to test individuals who are receiving a community correction order for hepatitis C. This study will use a new hepatitis C test that is performed with just a small droplet of blood collected via a fingerpick, and if an infection is identified, we can offer you treatment for your hepatitis C.

This Participant Information Sheet/Consent Form tells you about what we are planning to do and what’s involved for you, to help you decide if you want to participate.

Please read this information carefully. Ask questions about anything that doesn’t make sense. Before deciding whether or not to take part, you might want to talk to someone else for advice.

Being in this project is up to you. If you prefer not to be involved in the study, you don’t have to. It won’t change the medical care you receive now or in the future.

If you decide you will take part, you will be asked to provide written consent to participate. This means that you:

• Understand the information I give you about participating in this study

• Consent to take part in the research project

• 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?**

Hepatitis C is a virus infection that causes damage to the liver. Over many years this can cause scarring of the liver. If the scarring becomes severe, the liver can show signs of failure resulting in hospitalisation, liver cancer or death.

We now have medications available in Australia to treat hepatitis C. These medications are new but have been approved for treating hepatitis C in Australia since 2016. Usually this involves one to three tablets a day for 8-12 weeks and over 95% of people who take this treatment will be cured. Four weeks after your last tablet we do a blood test – if there is no hepatitis C virus found at this time, then you are cured. This stops any further scarring developing in the liver. It also means you can no longer pass on hepatitis C infection to other people (although you can get a reinfection).

At the moment, there aren’t any healthcare services set up to offer hepatitis C testing to people receiving a community correction order. As many people receiving a community corrections order have risk factors of hepatitis C, it is important that they have access to a service that offers hepatitis C testing and treatment if the person has a hepatitis C infection. Sometimes doing blood tests can be difficult, so we are using a finger prick test which also gives a result in 60 minutes. Some more blood tests may be required if this test is positive.

This new type of care will be offered from a mobile van parked next to community corrections offices. A nurse or doctor from St Vincent’s Hospital, or a peer worker from Harm Reduction Victoria will perform the hepatitis C test in the van. At the same time, they will ask you some questions about your life, health status and prior experience with hepatitis C. If the test shows you have a hepatitis C infection, we will talk to you about starting tablets to treat this infection which we can prescribe from the van. If you commence treatment, we’ll stay in touch with you either when you visit the van or over the telephone to help you commence and continue treatment. We’ll also contact you to remind you to get your blood test done to make sure you are cured four weeks after finishing your tablets.

This means we will be calling you to check on how you are going with treatment. We will provide your medications free-of-charge and also give you Coles Myer vouchers for getting tested and doing the questionnaires, as well as finishing your tablets and getting your finger prick blood test taken to test for cure. If this new way is shown to work well, we will keep this treatment service going for people who are receiving community corrections orders.

This research has been initiated by Dr Rebecca Winter, Professor Alexander Thompson and A/Prof Jacinta Holmes.

This research is being conducted and funded by The Department of Gastroenterology at St Vincent’s Hospital

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

Before you can be in this study, you will be asked to sign the bottom of this form to consent to participate. Deciding to participate in this study is your decision and will not affect the care you receive or your treatment in regard to your community corrections order.

If you decide to sign up to the study, it will involve the following:

All study participants:

* **Being tested for hepatitis C infection** – this will involve using a small needle, called a lancet, to prick the pad of your finger to draw a small amount of blood. This blood will be placed into a small cassette to perform the test, which takes around 60 minutes to run.
* **Answering a questionnaire** – while the hepatitis C test is running, one of our team members will ask you some questions to help us understand your general health, things that may have put you at risk of hepatitis C infection and if anything in your life has made it hard to get tested for hepatitis C previously.

If this test shows that you don’t have a hepatitis C infection, there is no further involvement for the study.

If the test shows that you currently have a hepatitis C infection, we will continue to follow you up in the van or via the telephone. If the test is positive, we will do the following things:

* Arrange some more blood tests required for starting hepatitis C treatment
* Discuss commencing hepatitis C treatment with you. If you choose to commence treatment, we will provide you with a script you can take to your local pharmacy or arrange medications to be brought over from St Vincent’s Hospital. You will not be required to bear the costs for these medications, we will arrange for these to be invoiced to the study.
* Either arrange a meeting at the van or call you four and eight weeks after starting treatment to check on how you are tolerating treatment, that you have enough tablets and aren’t getting any side effects.
* Arrange another finger prick test four to 12 weeks after finishing tablets to make sure the hepatitis C infection is gone.
* Invite you to do some more questionnaires to help us understand your experience on treatment and your life more broadly.

The questionnaires help us to understand how you are going during your community correction order and if anything in your life is making it hard to get or start hepatitis C treatment. As such they will ask you about:

* Your health
* Your housing
* Your social supports
* Your financial and employment situation
* Your drug use (if any)

All of the information you tell us is confidential and if you don’t want to answer a particular question you don’t have to.

You will be provided with reimbursement for your time completing the questionnaires in the form of a Coles Myer voucher. A $40 voucher will be offered at the end of the first questionnaire. If you complete treatment and undertake a second questionnaire and finger prick test 4-12 weeks after finishing your tablets, another $40 voucher will be offered.

There are no additional costs associated with participating in this research project. All medication, tests and medical care required as part of the research project will be provided to the participant free of charge.

You can call us at any time if you are worried about the project or have questions. After we have done your blood test 4-12 weeks after finishing treatment to make sure the infection is gone, there isn’t anything further you need to do for the study.

***Record Linkage,*** where we match your details with information from other databases (with your approval), is a part of the study - for participants who test positive or negative for hepatitis C infection. We will do this to record your use of health services and your contact with the criminal justice system. We will link your personal details to health service agencies such as the Australian Government Department of Health (or an accredited linking authority such as the Australian Institute of Health and Welfare) and Corrections Victoria. We will ask for information since the start of the C No More study in 2023 on:

* **Medicare**, from the Australian Government Department of Health (e.g. your attendance at health care services, the types of services you used and the medications you were prescribed)
* **National Death Register** (e.g. date and cause of death)
* **Periods of incarceration**,from Individual Management Plans held by Corrections Victoria (e.g. dates of imprisonment and release, type of imprisonment including on remand or sentenced, and type of release)
* **Periods of community supervision,** from Corrections Victoria (e.g. order start date, order end date, order end type)

We will only send information used to identify you, in a secure and confidential way, to these agencies. It may include Medicare number, first name, surname and middle initial (or a code made up of these), date of birth, gender and address. **Other information you give us in interviews will only be seen by the C No More team**. We will try to match your data regularly, depending on funding and questions of interest. You can withdraw consent to linkage to Corrections Victoria below.

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

To participate in the study, we require you to complete questionnaires (completed at the clinic van near the community corrections offices) and consider getting tested for hepatitis C infection.

If you sign up, you will do a questionnaire with a C No More researcher while we wait for the hepatitis C test to run. If you don’t want to wait for the result, we can call you the following day or arrange a time to meet you at the van.

If we find out that you have a hepatitis C infection, we will discuss commencing hepatitis C treatment with you. If you choose to start treatment, we can either provide you with a script or with the hepatitis C tablets directly. To make sure the hepatitis C treatment has worked and to ensure you are cured, a blood test looking for the virus should be done 4-12 weeks after finishing the tablets. There won’t be any more commitments for you to do after this blood test.

The only restrictions to participating in this study would be if you believe you will not be able to participate in the surveys or follow up asked of you.

**5 Other relevant information about the research project**

We aim to test lots of people for hepatitis C infection who are receiving community correction orders over an 24 month period. The researchers, who have an interest in the area of hepatitis C and prisoner health, will provide an opportunity for questions and discussion on aspects of their hepatitis C care and risk factors for reinfection. You should also discuss your liver health with a local doctor as well as being in this study.

**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 Corrections Victoria. This study is completely independent of your community correction order and has no impact at all on that.

Whatever your decision, you are still able to discuss your personal risks for hepatitis C infection with your GP and arrange testing through them.

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

You do not have to take part in this research project to be tested for hepatitis C or to receive treatment if you have a hepatitis C infection. If you don’t want to be involved with this project, you can still see your local doctor to discuss testing for hepatitis C infection.

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

We cannot guarantee or promise that you will receive any benefits from this research. The greatest benefit will be to know if you have a hepatitis C infection. This will allow you to get treated for hepatitis C and stop the formation of scar tissue in the liver.

You will also be involved with a team of doctors and nurses who really want to make hepatitis C testing easier to access for all people, and treat those people who have a hepatitis C infection. You will receive vouchers along the way for being involved in the study, and we will assist in covering the costs of your hepatitis tablets.

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

There is a minor risk 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 slight risk of infection and /or inflammation of the vein (phlebitis). If this happens it can be easily treated. The finger prick test is generally even safer and these risks are reduced further.

Sometimes when completing questionnaires or discussing more sensitive topics, you might become upset about what is discussed. If this occurs, the study team member 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.

In general, all medications for hepatitis C are very safe and have very few side effects. We have treated over 2000 prisoners and less than 5% have had side effects.

In those who did it was generally mild symptoms of nausea, vomiting and diarrhoea, or fatigue and headaches.

If you get these side effects, you can call us to discuss this. We will provide you with a telephone number which you can call at any time to discuss your symptoms with a nurse or doctor in the research team. They 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.

**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 tell others 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. If we were ever required to do so, we would do our best to notify you before disclosing it.

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

Only one “traditional” blood test, called venepuncture, where the needle is inserted into the vein, will be done at the beginning of the study for those people whose finger prick test shows they have a hepatitis C infection. The sample will be tested at St Vincent’s Hospital and is subject to the same regulations as any other test collected through this service.

This blood will be taken to confirm hepatitis C infection, as well as to check for any other blood borne viruses or any other information we may need to know prior to treatment initiation.

**11 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, your doctor will tell you about it and discuss with you whether you want to continue in the research project.

If you decide to withdraw, your study 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 study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

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

If you have a hepatitis C infection, you will not require any additional therapies to treat it beyond what is prescribed by the research team. You can take tablets for other health issues during the trial period. However, because some other medications can potentially interact with the hepatitis C drugs, it is important to tell us about any treatments or medications you may be taking, 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 these during your participation in the research project. Your study doctor 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 you want to withdraw from the project, you can discuss it with a member of the team before you withdraw. That way we can work through your reasons for wanting to pull out. 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 personal 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.

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

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

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

At the end, you will be provided with some information about reducing your risk of 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 liver disease we will refer you to a convenient liver clinic for your ongoing care.

**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 research team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential.

Your clinical and survey data will be collected electronically on a tablet using Research Electronic Data Capture (REDCap), a secure web application. These data will be hosted by the Burnet Institute, password protected and accessible only to members of the study team. 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 seven years, in line with research requirements. It will be shared only with your permission, or if we are required to share it by law. We have told you the reasons this could happen above. It is expected that the results will also be published as a report and presented at meetings. Information will be provided in such a way that you cannot be identified.

Please contact one of the researchers if you would like to access any of your study information. You can either use our study phone number that we will give you or the contact details listed in this form.

**17 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 and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

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

This research is being done by the Department of Gastroenterology at St Vincent’s Hospital Melbourne. The primary investigators are Dr Rebecca Winter, Professor Alexander Thompson and A/Prof Jacinta Holmes*.*

You will be compensated for your time and will receive reimbursements (vouchers) to complete questionnaires, however you will not otherwise benefit financially from your involvement in this research project.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to St Vincent’s Hospital, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

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

**19 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group 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 Melbourne*.*

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007, updated 2018). 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 your question.

If you want more information about the project or if you have a medical issue (like a side effect), you can contact Dr Jacinta Holmes on (03) *9231 2211* or any of the following people:

**Clinical contact person**

|  |  |
| --- | --- |
| Name | *Dr Jacinta Holmes* |
| Position | *Gastroenterologist, St Vincent’s Hospital Melbourne* |
| Telephone | *9231 2211* |
| Email | *jacinta.holmes@svha.org.au* |

**Project coordinator**

|  |  |
| --- | --- |
| Name | *Dr Rebecca Winter* |
| Position | *Research Coordinator* |
| Telephone | *0434 401 092* |
| Email | *Rebecca.winter@svha.org.au* |

If you have any complaints about any aspect of the study or the way in which it is being conducted you may contact the Patient Liaison Officer at St Vincent’s Hospital (Melbourne).

**Complaints contact person**

|  |  |
| --- | --- |
| Position | *Patient liaison officer* |
| Telephone | *(03) 9231 1954* |
| Email | [PLO@svhm.org.au](mailto:PLO@svhm.org.au) |

If you have any questions about your rights as a research participant, then you may contact the Executive Officer, Research at St Vincent’s Hospital (Melbourne).

|  |  |
| --- | --- |
| Reviewing HREC name | *St Vincent’s Hospital Melbourne HREC* |
| HREC Executive Officer | *Executive officer of research* |
| Telephone | *(03) 9231 6970* |
| Email | [*research.ethics@svhm.org.au*](mailto:research.ethics@svhm.org.au) |

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



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

|  |  |
| --- | --- |
| **Title** | **C No More:** A prospective pilot study to evaluate the feasibility of hepatitis C point of care testing and treatment initiation for individuals receiving a community corrections order. |
| **Protocol Number** | 1.2 |
| **Project Sponsor** | St Vincent’s Hospital Melbourne |
| **Principal Investigators** | Dr Rebecca Winter, Prof Alexander Thompson  A/Prof Jacinta Holmes |
| **Associate Investigator(s)** | Dr Tim Papaluca  Prof Mark Stoové  Mr Sione Crawford  Ms Jane Dicka  Dr Shelley Walker  Ms Samara Griffin (student researcher) |
| **Location** | St Vincent’s Hospital Melbourne |

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand. Yes No

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

Yes No

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to St Vincent’s Hospital Melbourne concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential. Yes No

I have had an opportunity to ask questions and I am satisfied with the answers I have received. Yes No

I consent to point-of-care hepatitis C RNA testing using a blood sample collected via finger prick testing Yes No

I consent to participating in healthcare related questionnaires Yes No

I understand I may contacted on my telephone if the study team need to follow up results or the outcome of any prescribed hepatitis C treatments. Yes No

I give permission for my test results and treatment information to be shared with Victorian prison hepatitis services in the event that I am incarcerated during the study period, to ensure my care can be continued while in prison. Yes No

I consent to the use of staff reflections on my interactions with the service for the purposes of service improvement and evaluation of the nurse- and peer-led service, and I understand my name will not be used in the analysis of these reflections. Yes No

I authorise and give consent for Corrections Victoria to release information about my history of community supervision and/or incarceration (through release of information from Corrections Victoria, including my Individual Management Plan) and understand that this information will be collected, stored and analysed only for the purposes of the C No More project. Yes No

I consent to the study team contacting me to invite participation in further healthcare related questionnaires and/or evaluation of the *C No More* clinic Yes No

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Verbal consent recorded? (y/n) |  | | Date |  |  |
|  |  |  | |  |  |  |
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| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Witness\* to Participant’s Signature (please print) | |  | | |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

Witness is only required in the event that participant cannot read or understand the PICF in keeping with the Victoria Government Clinical Trials and Research Guidelines.

**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.

|  |
| --- |
| **Participant ID:** |

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| ***D: PARTICIPANT CONSENT FORM***  Consent to release of Medicare and/or Pharmaceutical Benefits Scheme (PBS) claims information for the purposes of the C No More Study. |

|  |
| --- |
| **Important Information**  Complete this form to request the release of personal Medicare claims information and/or PBS claims information to the C No More Study.  Any changes to this form must be initialled by the signatory. Incomplete forms may result in the study not being provided with my information.  By signing this form, I acknowledge that I have been fully informed and have been provided with information about this study. I have been given an opportunity to ask questions and understand the possibilities of disclosures of my personal information. |

|  |
| --- |
| PARTICIPANT DETAILS   1. Mr □ Mrs □ Miss □ Ms □ Other   Family name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_First given name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Other given name (s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date of birth: DD/MM/YYYY  2. Medicare card number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  3. Permanent address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Postal address (if different to above): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  AUTHORISATION  4. I authorise the Department of Health to provide my:   Medicare claims history OR   PBS claims history OR  Medicare & PBS claims history  to the C No More study.  DECLARATION  I declare that the information on this form is true and correct.  5. Signed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (participant’s signature)  Dated: DD/MM/YYYY\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

A sample of the information that may be included in your Medicare claims history:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Date of service | Date of Processing | Item number | Item description | Provider charge | Schedule Fee | Benefit paid | Patient out of pocket | Bill type |
| 20/04/09 | 03/05/09 | 00023 | Level B consultation | $38.30 | $34.30 | $34.30 | $4.00 | Cash |
| 22/06/09 | 23/06/09 | 11700 | ECG | $29.50 | $29.50 | $29.50 |  | Bulk Bill |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Scrambled ordering Provider number\* | Scrambled rendering Provider number\* | Date of referral | Rendering Provider postcode | Ordering Provider postcode | Hospital  indicator | Provider derived major speciality | Item category |
|  | 999999A |  | 2300 |  | N | General Practitioner | 1 |
| 999999A | 999999A | 20/04/09 | 2300 | 2302 | N | Cardiologist | 2 |

\* Scrambled Provider number refers to a unique scrambled provider number identifying the doctor who provided/referred the service. Generally, each individual provider number will be scrambled and the identity of that provider will not be disclosed.

A sample of the information that may be included in your PBS claims history:

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Date of supply | Date of prescribing | PBS item code | Item description | Patient category | Patient contribu tion | Net Benefit | Scrambled Prescriber number\* | Pharmacy postcode | Form Category |
| 06/03/09 | 01/03/09 | 03133X | Oxazepam Tablet 30 mg | Concessional Ordinary | $5.30 | $25.55 | 9999999 | 2560 | Original |
| 04/07/09 | 28/05/09 | 03161J | Diazepam Tablet 2 mg | General Ordinary | $30.85 |  | 9999999 | 2530 | Repeat |

|  |  |  |
| --- | --- | --- |
| ATC Code | ATC Name | Prescriber derived major speciality |
| N05 B A 04 | Oxazepam | General Practitioner |
| N05 B A 01 | Diazepam | Psychiatrist |

\* Scrambled Prescriber number refers to a unique scrambled prescriber number identifying the doctor who prescribed the prescription. Generally, each individual prescriber number will be scrambled and the identity of that prescriber will not be disclosed.



**Form for Withdrawal of Participation –**

*Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | **C No More:** A prospective pilot study to evaluate the feasibility of hepatitis C point of care testing and treatment initiation for individuals receiving a community corrections orders. |
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| **Location** | 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 Melbourne.*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

**Circumstances of withdrawal**

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**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.