Participant Information Sheet/Consent Form

Interventional Study – *Adult providing own consent*

St Vincent's Hospital (Melbourne)

Title	**RE**nal transplant of H**C**VRNA+ donor kidneys into HCVRNA- recipients: A Pilot Study (the **R**Eplace Study)
Protocol Number	
Project Sponsor	Investigator Initiated
Coordinating Principal Investigator/ Principal Investigator	Associate Professor David Goodman
Location	St Vincent's Hospital (Melbourne), 41 Victoria Parade, Fitzroy, 3065, Victoria

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you have a diagnosis of renal failure and are on the kidney transplant wait-list.

We are asking you to consider joining a study where kidneys with hepatitis C will be offered to people like you who do not have hepatitis C. Hepatitis C is a virus that infects your liver, and over many years (10-30), can lead to scarring of your liver, which can develop into end-stage scarring (called cirrhosis), which could lead to liver failure, cancer, or death. Rarely, hepatitis C can cause inflammation in other parts of your body, including your skin or kidneys.

If you receive a kidney with hepatitis C, we would give you medicine to treat the hepatitis C virus. The treatments for hepatitis C are highly effective. In other studies, these medicines have cured more than 95% of patients with chronic hepatitis C, including people who have been treated for chronic HCV following liver / renal transplantation. However, we do not know whether these medicines will be as effective for someone who becomes infected with hepatitis C due to due to a hepatitis C-infected kidney transplant.

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

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 totally voluntary. If you do not wish to take part in this study, receive the best possible usual care and your position on the transplant waiting list will not be affected in any way.

If you decide to take part in the research project, you will be asked to sign the consent section. By signing the form you are telling us and agreeing that you:
• Understand both risk and benefits of 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?

Kidney transplant is a life-extending, life changing procedure for people with renal failure. Transplanted kidneys come from either a living donor or a deceased donor. Currently the average waiting time for a deceased donor kidney is approximately 3-4 years, but the wait time depends on multiple factors which vary from patient-to-patient. Since kidney transplantation improves life expectancy compared to remaining on dialysis, the best available treatment for kidney failure is transplantation after consideration of all the risks and benefits. Transplantation is recommended if your doctor considers that the benefits outweighs the risks.

Unfortunately the demand for donor kidneys is greater than the supply and therefore patients must continue on dialysis while they wait for a transplant. It is known that extended periods on dialysis has detrimental effects on people's health in the long term. The goal of renal failure treatment is to transplant individuals as soon as safely possible.

In the past, kidneys from a hepatitis C positive donor have been not been used for donation into a person who does not have hepatitis C due to the almost certain infection of the recipient with hepatitis C, and treatment options at that time were relatively ineffective and could not be safely given to transplant recipients. Recent advances in the treatment of hepatitis C (new Direct Acting Antiviral or DAA therapy) means that hepatitis C infected kidneys are now being considered for transplantation. A recent study in America has shown that subjects can have a kidney transplant, using a hepatitis C positive kidney and can then be successfully treated (eradication of hepatitis C infection), following the transplant. Over 30 transplants have taken place in the study, with all transplant recipients receiving hepatitis C treatment and all successfully being treated for hepatitis C (that is, clearing the virus from their blood).

HCVRNA-positive donor kidneys are currently under-utilized. In the era of safe and effective treatment for hepatitis C infection, hepatitis C positive kidneys should be evaluated as a means to expand the donor kidney pool, including being used in hepatitis C-negative recipients. This strategy is particularly attractive for high risk groups on the transplant waiting list who would benefit from quicker renal transplantation.

In this study, people who receive a transplant kidney infected with hepatitis C will be treated with a pill made of Glecaprevir and Pibrentasvir after the transplant.

The research has been initiated by Associate Professor David Goodman, Professor Alexander Thompson and Professor Frank Ierino.

This study is funded by the Gastroenterology Department and Renal Department (St Vincent's Hospital, Melbourne). The study medication is available on the PBS. Dispensing will be organised in accordance with each hospital pharmacy department's standard practice.

The goals of this project are to:

i) Determine the effectiveness of DAA at preventing transmission and infection with hepatitis C when organs from Hep C infected Donors are transplanted into uninfected recipients
ii) Reduce the waiting time on dialysis which needs to be balanced against the risk of being infected with hepatitis C

How long will I be in the study?

Participants will be in the study while they wait for a transplant (estimated 6 – 12 months, but could be longer), and for approximately 6 months following the transplant.

3 What does participation in this research involve?

Currently you have kidney failure and have been assessed by the transplant team as being eligible to be added to the deceased donor transplant waiting list. By enrolling in this study, you are choosing to be added to a second waiting list (in addition to the standard waiting list). This second waiting list is for those who agree to accept a transplant with a hepatitis C infected kidney. Choosing to go onto this second waiting list is entirely your personal, voluntary decision. If you choose not to enrol in this study, your place on the standard waiting list and your care by the transplant team will not be affected. Even if you sign this consent form, you will still have the opportunity to decline a kidney transplant from a hepatitis C infected donor at the time it is offered to you.

Your kidney transplant will proceed as normal (as if you weren't in the study). You will receive the same care as every transplant patient. The Gastroenterologist study doctor will closely monitor your blood results following the transplant. If your blood results indicate early hepatitis C infection, you will be commenced on the study treatment. This s a tablet combining two drugs Glecaprevir and Pibrentasvir, The tablet is taken daily for 12 weeks and is successful in eliminating hepatitis C in most of those treated. This combination treatment has been shown to be safe and very effective in the setting of anti-rejection treatments following liver and kidney transplant. It is well tolerated and has minimal problems with drug-drug interactions. This combination is also very safe and effective in people with poor renal function.

This study involves three phases

1. **Screening phase:**

The screening period is the period of time when it is determined if you are eligible to be in the study. This will take place before you receive the kidney transplant. During the screening phase, you will discuss what participation in the study means and will have the opportunity to ask as many questions as you need to fully understand the study. Once you fully understanding the requirements of the study and any potential risks and benefits and before any study-related tests or procedures have occurred, you will sign and date this consent form. You will then progress through a screening process to ensure you are eligible for the study.

The following examinations and tests will be performed as part of the screening process for the study. They will be in addition to any tests and procedures you will be required to have as part of your work-up for the kidney transplant. Every effort will be made to conduct the additional tests and procedures at the same time as your scheduled renal outpatient appointments.

- Complete physical exam including height, weight and vital signs (blood pressure, heart rate, temperature, and breathing rate)

- Blood Tests – see table below for required study specific blood tests

- Radiological Tests

    - Fibroscan – This is a test to measure the stiffness of the liver. To perform it a jelly is placed on the skin overlying the liver, a probe is then applied which delivers a light pulse to the skin. This pulse speed is used to measure how stiff the liver is as a marker for how much scar tissue is in it.

The proposed blood tests include a screening test for HIV (also called the 'AIDS' virus) and hepatitis B (HBV). This is because the study doctors need to know whether you also have HIV or HBV infection. You will receive information and counselling before the tests. If a test shows you have HIV and/or HBV, you will have follow-up counselling and medical advice. If your test results are positive, the study doctors may be 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. If you have HIV or HBV, you will not be eligible to participate in this study.

2. The Waiting List

Following screening, if it is determined that you are eligible for the study, we will update your transplant medical record to show that you are willing and eligible to receive offers of kidneys with hepatitis C. The relevant member of the transplant team will also be notified.
You will remain on the kidney transplant list. You will have the same tests/procedures during this time as anyone else on the transplant list. During this time, you will still be able to receive offers of kidneys from donors without hepatitis C.

If you do receive an offer of a hepatitis C positive kidney, you can decide with your transplant doctor whether or not you want to accept the kidney.

If you do not get a kidney transplant from a donor with hepatitis C during the study period, or if you receive a kidney without hepatitis C, then you will not need any hepatitis C associated treatments and you will not need to do any of the tests/procedures outlined in this Information Sheet.

If you do receive an offer of a kidney with hepatitis C and you do decide to accept the offer, you will need to have the tests and procedures as set out in this Information Sheet, and receive the anti-HCV treatment.

3. <u>The Transplant</u>

Having agreed to the hepatitis C infected kidney, the transplant will go ahead as per the hospital's standard policies and procedures.

The Gastroenterology study staff will see you on Day 7 post-transplant. You will have a blood test that will measure any hepatitis C virus in your blood. If this test is positive, you will be commenced on treatment with Glecaprevir and Pibrentasvir for 12 weeks (this visit when you commence treatment is called the baseline visit).

The study drugs are combined into one tablet All participants will receive glecaprevir/pibrentasvir fixed dose combination (300mg/120mg) three tablets once daily for 12 weeks. Glecaprevir/pibrentasvir is three tablets taken by mouth once daily with food. Each tablet should be swallowed whole. It is recommended that you take the tablets at approximately the same time every day.

If you miss a dose, you should take the missed dose of study medication as soon as possible during the same day. However, no more than three tablets of glecaprevir/pibrentasvir should be taken on any one calendar day

The medical management of your transplant will not be affected by the introduction of the hepatitis C treatment. You will be reviewed in the same way as any other kidney transplant recipient.

Study Schedule of Procedures

Visit schedule and assessments (for this study only – not including specific tests required for pre and post transplantation):

Study procedure	Screening	Baseline (visit 2)	On-treatment			Post-treatment		
Week			**Week 1 Day 7**	**Week 4 Day 28**	**week 12 Day 84**	**4x**	**12x**	**24x**
ECG	X	X				X		
FibroScan	X						X	
Serum chemistry panel (LFTs, U&Es)	X	X	X	X	X	X	X	X
Pregnancy Testing (F)	X							
HIV, HBV, ANA Serology	X							
AFP Serology and Ultrasound	X							
HCV genotype determination	X	X						
HCV RNA Quantification[a] (COBAS Taqman v2.0)	X	X			X	X	X	X
HCV NS3/NS5 sequencing		X						
Stored serum sample for virological sequencing[b]		X		X	X	X	X	X

Key:
[a] : for subjects who are HCV RNA negative at Day 7 post-transplant, HCV RNA serum sample will be collected at post-transplant visits Week 4, week 12 and week 24
[b] : samples will be stored at the Victorian Infectious Diseases Reference Laboratory.

5 Other relevant information about the research project

We aim to recruit 10 patients to this study, from a number of public hospitals in Victoria. After each transplant there will be a safety review of that participant's procedure, treatment and outcomes. A decision will then be made to proceed with the next transplant.

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 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 St Vincent's Hospital (Melbourne).

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. If you do not take part, the medical management of your renal disease will continue and you will remain on the general transplant waiting list as part of usual care. Your usual care will not be affected in any way. .

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include receiving a kidney transplant earlier than would have otherwise occurred.

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

The main risk of this study is that you will become infected with hepatitis C.

1. **Risks related to transplantation with a hepatitis C positive kidney.**

Liver problems:
You need to know that it is possible that the treatment for Hepatitis C may not work as well after a transplant as it has worked in people who did not have a transplant**. It is also possible that after the kidney transplant, Hepatitis C infection could cause you serious health problems, including liver failure or death.** Hepatitis C can very rarely cause severe liver inflammation in the first few weeks to months after infection, or the virus can cause scarring and failure of your liver over many years.

In the short term, infection with hepatitis C can cause a flu-like illness that includes fatigue, nausea, fever, abdominal pain, vomiting, joint pain, and jaundice (yellow skin). In very rare circumstances, acute infection with hepatitis C can cause severe inflammation or even liver failure, including a condition called fibrosing cholestatic hepatitis. The risk of this complication in patients without hepatitis C who receive a transplant from a donor with hepatitis C is unknown. This complication can be treated.

Liver failure can cause leg swelling, yellow skin, uncomfortable feelings of itchiness, bleeding, breathing problems and the abdomen to fill with fluid. Liver failure can also cause death. Based on the limited data available, we believe that it would be very rare for someone in the study to experience liver failure in the first months after transplantation, when we will be giving anti-HCV treatment.

These risks should be prevented by effective treatment of hepatitis C – such events have not been observed in the small number of people enrolled in other studies to date.

If your hepatitis C cannot be cured with the first-line or second-line treatments (as offered in this study), over many years there may be continued inflammation and scarring of your liver, that may lead to cirrhosis and eventually liver failure. Longer term infection with hepatitis C increases the risk of developing liver cancer, liver failure requiring a liver transplant, or death.

Additional risks of hepatitis C

Hepatitis C can cause other types of inflammation in your body, such as arthritis, rash, anaemia and inflammation damage to your kidney transplant. However, these problems should respond to effective treatment for the hepatitis C virus.

There may also be a small risk of developing Focal and Segmental Glomerulosclerosis (FSGS) after receiving a kidney from a donor with hepatitis C. FSGS is a disease that harms the filters of the kidney and causes the patient to lose protein in their urine. This condition can also develop in patients who do not have hepatitis C. Long term, FSGS may cause kidney failure. After transplant, we will monitor all patients for conditions like FSGS. We will also offer treatments for FSGS which can help some patients.

2. Risks related to study medications

Most of the side effects experienced by patients taking glecaprevir/pibrentasvir are considered to be mild. To date 554 participants have taken glecaprevir/pibrentasvir in phase III studies. The most common side effects were headaches (17%), fatigue (12%) and nausea (11%). No participants stopped treatment due to side effects.

It is not expected that you will have any or all of these side effects. Other side effects may occur that are not listed here or were not seen before. Please speak to your study doctor for more information. Side effects are usually temporary and can often be treated. However, it is very important that you report all side effects to your study nurse at any time during the study as it is possible that side effects may suggest a serious or fatal health problem.

Glecaprevir/pibrentasvir may interact with other medication you are taking, including immunosuprressants. Glecaprevir/pibrentasvir may require dose adjustment of your immune-suppressive medication post-transplant, but they are not predicted to cause drug-drug interactions that may interfere with necessary immunosuppression and contribute to rejection of your kidney transplant.

Glecaprevir/pibrentasvir is very effective – in clinical trials the efficacy of glecaprevir/pibrentasvir for treating hepatitis C was 99% in transplant recipients. There is a very small risk that treatment may not be effective, or may not be possible due to complications post-transplant that are unrelated to this study. In this case, there are other treatment regimens that are available that would be suitable as second-line treatment. Some of these treatments are not recommended in people with very poor kidney function, and there may be a waiting period post-transplant before second-line treatment could be started.

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, 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.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get. Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. Please tell the study doctor or nurse about any new symptoms or side effects. Your study doctor will discuss the best way of managing any side effects with you. The study doctor may need to stop your treatment.

Resistance of the virus to Hepatitis C treatments
We do not know how effective glecaprevir/pibrentasvir will be in eliminating hepatitis C after a transplant, in your circumstances. Determining the medication's effectiveness is one of the purposes of the study.

One of the main risks of participating in this study is the possibility that the hepatitis C may become resistant to the study medication and this may limit your future treatment options. The likelihood of resistance developing is higher if you miss study drug doses or do not follow the study recommendations. If you show possible resistance to the study drugs by having an increase in your hepatitis C viral load while on treatment, you will be asked to return to clinic to repeat the hepatitis C viral load test. We may need to change your treatment plan.
Very few people (approximately 5%) have a mutation of a type of hepatitis C that puts them at risk of resistance. We will conduct a test to determine if you are at risk for this. There is a risk that this test is not 100% accurate. If the test gives the wrong result, your chances of being cured may be lower and you may need additional treatment.

If you do not respond to treatment with glecaprevir/pibrentasvir after 12 weeks, we will offer you a different set of medications.

Reproductive Risks

Pregnancy:
Extreme care must be taken to avoid pregnancy in female participants during this study and for up to 30 days following completion of study treatment.

Female Participants

Female participants need to avoid pregnancy during the course of the study and for a period of 30 days after completion of the study. You should speak to the study doctor about the need to avoid pregnancy during this study.

Breastfeeding:
It is not known whether glecaprevir/pibrentasvir (or their metabolites) are excreted in human breast milk. Mothers should not breastfeed while taking glecaprevir/pibrentasvir.

3. Risks related to study procedures and tests

Blood taking
There is a potential risk from when blood is taken of pain and bruising at the site; also fainting. There is a very rare risk of infection. Discomfort from this procedure is generally short-lived and serious side effects are extremely rare.

FibroScan
A FibroScan will be used to measure the amount of liver fibrosis (scarring) in a non-invasive and painless manner. Performed with you lying in bed, a machine generates a pulse wave at the skin surface, which spreads through the liver. The speed of the wave can be measured by ultrasound. Generally the whole process can be completed in less than 10 minutes. The FibroScan will be performed by a trained technician or one of the liver study doctors. There are no potential discomforts or risks involved with having a FibroScan.

There are no additional costs associated with participating in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you free of charge.

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.

10 What will happen to my test samples?

Your samples will be stored in a secure facility. Only authorized staff are allowed to enter the facility. When blood samples are taken a unique number will be applied to your sample to protect your information. Your samples will be re-identifiable via a code that will be generated and link the sample with personally identifiable information. This will be maintained in a secure system under strict supervision.

Only your study doctor will have the information that matches the code to your identifying information, such as your name, address and phone number. Your study doctor will keep the information that matches the code to this identifying information in a safeguarded database. Only very few, authorized people, who have specifically agreed to protect your identity, will have access to this database. All other researchers and personnel, including those who will be working with your samples and medical information, will not have access to any of the identifying information about you.

No research will take place using your samples and information unless that research is first reviewed and approved by a Human Research Ethics Committee, which will determine whether the benefits of the research outweigh the cost to you and your privacy.

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 study 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?

Whilst you are participating in this research project, you must not take any medications other than those prescribed for you by your treating doctors. It is important to tell your study doctor 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 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 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 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 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.

15 What happens when the research project ends?

Once the research project ends you will not be given glecaprevir/pibrentasvir. If you did not clear the virus while on the study or you become reinfected during the study you may be eligible for retreatment with government subsidised treatment (standard of care treatment) .Please ask your study doctor for more information about what the re-treatment options are.

Your medical management with the Renal Unit will continue as per standard protocols and processes for transplant patients..

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 study doctor and relevant research staff 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 blood samples will be coded with your participant number. This code number links your sample and results to your name. The researchers doing the tests will not know your identity from this code number. The Study Doctor will keep the list, which links the code number to your name. All samples will be stored in a secure facility. Only authorized staff are allowed to enter the facility. Your samples may be transferred to other research partners working with the study Doctors.

Only your study doctor will have the information that matches the code to your identifying information, such as your name, address, phone number, or social security number. Your study doctor will keep the information that matches the code to this identifying information in a safeguarded database. Only very few, authorized people, who have specifically agreed to protect your identity, will have access to this database. All other researchers and personnel, including those who will be working with your samples and medical information, will not have access to any of the identifying information about you.

The results will not be provided to any insurance company, your employer, your family or any of your doctors without your permission. Your samples may be stored for testing for up to 15 years after the completion of this research study, or until the sample is gone.

If any future testing is performed using your samples as described in this consent, no additional informed consent will be obtained from you and you will not be notified.

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.

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 the institution relevant to this Participant Information Sheet, St Vincent's Hospital (Melbourne), 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.

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

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.

Any information obtained for the purpose of this research project and for future research as described above 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 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.

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) on Telephone: 03 9231 3108. You will need to tell the Patient Liaison Officer the name of the person who is noted above as principal investigator.

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) on Telephone: (03) 9231 2394. Please quote study number HREC/18/SVHM/180.

18 Who is organising and funding the research?

The research has been initiated by Associate Professor David Goodman, Professor Alexander Thompson and Professor Frank Ierino.

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 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.

20 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information 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 doctor, Associate Professor David Goodman on 03 9231 2211 (hospital switchboard). Ask for Associate Professor Goodman pager # 502; or any of the following:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Human Research Ethics Committee D (HREC-D) St Vincent's Hospital (Melbourne)
HREC Executive Officer	*Executive Officer - Research*
Telephone	*03 9231 2394*
Email	*Research.ethics@svhm.org.au*

Local HREC Office contact (Single Site - Research Governance Officer)

Position	*Executive Officer - Research*
Telephone	*03 9231 2394*
Email	*Research.Ethics@svhm.org.au*

Consent Form

Title	**RE**nal transplant of H**C**VRNA+ donor kidneys into HCVRNA- recipients: A Pilot Study (the **R**Eplace Study .
Protocol Number	
Project Sponsor	Investigator Initiated
Coordinating Principal Investigator/Principal Investigator	Associate Professor David Goodman
Location	St Vincent's Hospital (Melbourne), 41 Victoria Parade, Fitzroy, 3065, Victoria

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 *St Vincent's Hospital (Melbourne)* 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.

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 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.

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

Title	**RE**nal transplant of H**C**VRNA+ donor kidneys into HCVRNA- recipients: A Pilot Study (the **R**Eplace Study
Protocol Number	
Project Sponsor	Investigator Initiated
Coordinating Principal Investigator/ Principal Investigator	Associate Professor David Goodman
Location	St Vincent's Hospital (Melbourne), 41 Victoria Parade, Fitzroy, 3065, Victoria

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 _____

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.

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.