*Insert Header with institution’s name or institution’s letterhead*

**Participant Information Sheet/Consent Form**

**Interventional Study** –*Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | Evaluation for cirrhotic cardiomyopathy: A prospective study of global cardiac function in decompensated cirrhosis and its clinical significance |
| **Short Title** | Cirrhotic cardiomyopathy study |
| **Coordinating Principal Investigator/Principal Investigator** | Dr. Jeyamani Ramachandran |
| **Associate Investigator(s)**  *(Site Principal Investigator at Lyell McEwin Hospital )* |  |
| **Location** *(where CPI/PI will recruit)* |  |

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

**1 Introduction**

You are invited to take part in this research study because you have been diagnosed with a chronic liver disease with scarring known as cirrhosis of the liver. This study involves evaluating cirrhotic patients for heart abnormality known as cirrhotic cardiomyopathy (CCM) that is peculiar liver cirrhosis with new better tests.

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

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

Participation in this research is voluntary. If you do not wish to take part, you need not have to. You will receive the best possible care whether you take part in this study or not.

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

• understand what you have read;

• consent to taking part in the research project;

• consent to having 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?**

Patients with cirrhosis may have a type of cardiac abnormality called cirrhotic cardiomyopathy (CCM). This can be silent without any symptoms. This condition can affect as many as 50% of patients with cirrhosis and may also lead to heart failure at times of stress. This may occur during or immediately after certain important procedures performed in the routine care of cirrhosis, such as liver transplantation (LT), wherein the afflicted liver is replaced surgically by a healthy liver or during some invasive procedures performed for complications of liver cirrhosis ) or during a severe episode of infection. It can also lead to kidney failure and affect survival. Diagnosis of CCM would result in identifying patients at risk and then closely monitoring them to avoid worsening of the heart disease, as well as careful monitoring during and after LT. r.

The purpose of this study is to analyse new echocardiographic (the use of ultrasound to examine the structure and functioning of the heart for abnormalities and disease) parameters that are shown to be sensitive measures of early cardiac dysfunction. This study is expected to identify patients at risk of cardiac failure at times of stress on exposure to certain medications,) and proceduresperformed to address complications of liver cirrhosis.

We are performing this study with the aim of optimising the treatment of cirrhotic patients who are at risk of CCM. This research has been initiated and coordinated by Dr. Jeyamani Ramachandran, Consultant in the Hepatology and Transplant Medicine Unit in Flinders Medical Centre, South Australia, and a Senior Researcher at Flinders University. In Lyell McEwin Hospital, it will be coordinated by Dr. Asif Chinnaratha. These researchers are supported by a highly competent team of cardiologists and echocardiographers.

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

If you choose to take part in this study, blood samples will be collected from you at the time of consent. After obtaining consent, your clinical details including aetiology of liver disease and the list of medications including the dose of beta blockers will be recorded. Blood pressure and heart rate will be noted. Liver function tests and cardiac function tests will be done.

This will be followed by an electrocardiogram (ECG) and echocardiography( echo) within the next 4 weeks. For patients undergoing LT assessment, this is a standard procedure. If you are not considered for LT, this will be an extra procedure for you. Both these tests are non-invasive. If the echo study is normal at rest, then you may be subjected to a stress echo test with a medication called dobutamine that will make the heart work harder and faster as during exercise, to uncover any hidden cardiac problems. It is known as dobutamine stress echocardiogram (DSE). This test may be done on the same day of the routine echocardiogram or within the next 2 weeks.

DSE is minimally invasive and involves an intravenous administration of dobutamine and measurement of echocardiographic parameters under its effect. The procedure will be performed under close monitoring and with much smaller doses of dobutamine than is normally used. A cardiologist will be present during the DSE and continuous monitoring of your ECG, blood pressure and cardiac images will be undertaken. You will be asked throughout the testing how you are feeling and if you are feeling unwell if you would like to proceed. If you develop any undesirable cardiac side effects such as rhythm disturbances, the procedure will be stopped and you will be reviewed by the cardiologist and managed accordingly.The management may include administration of medications and hospitalisation to address the complications.Thus, any complication will be promptly identified and addressed.

In those study participants detected to have abnormal echo before LT, the tests will be repeated 12 months afterwards to assess the reversibility of CCM.

Any cardiac abnormality incidentally detected during these tests will be addressed with referral to a cardiologist. If you are detected to have CCM, you will be carefully managed as recommended by cardiologists. Your GP will be updated in case of any significant developments during the study.

There are no additional costs associated with participating in this study, nor will you be paid. However, if you were to make visits to the hospital exclusively for the study purpose unrelated to your clinical needs , we will be happy to reimburse your parking charges.

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

A total of 80 patients are expected to participate in this study at two hospitals:

1. Flinders Medical Centre
2. Lyell McEwin Hospital

**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. Whether you take part or not, your medical care will be the same. 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. You are free to withdraw from the study at any time.

**6 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 decide not to participate, your medical care will not be affected in any way.

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

There is a possibility that we may be able to uncover subtle cardiac dysfunction that might occur as a part of your liver condition in this research. If so, you will be managed as per routine treatment recommendations. In addition, any cardiac condition that is incidentally detected on echocardiogram or DSE will result in appropriate cardiac referral.

We cannot guarantee or promise that you will receive any benefits from this research; however, information gained from this study may help us to improve the services provided to you and other cirrhotic patients.

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

The risks associated with the study include:

* Discomfort during the blood-taking process/venipuncture for the blood tests, including occasional bself limiting bruising at the site of puncture may occur.
* ECG and echocardiogram are non-invasive tests. May occasionally involve skin irritation due to disposable electrode placement during ECG.
* Intravenous cannula insertion if DSE is required; However, DSE may be a part of your routine clinical care If you are worked up for LT.
* During DSE, there is a very small chance of adverse events, such as nausea, vomiting, tremors, low blood pressure, cardiac rhythm abnormalities and an extremely rare incidence of death. However, the incidence of complications is extremely low in those without any ischemic heart disease and with a normal resting study. You will be chosen for this procedure only if your resting echo is normal and there is no obvious evidence of ischemic heart disease. A cardiologist will be present during the DSE and continuous monitoring of your ECG, blood pressure and cardiac images will be undertaken. You will be asked throughout the testing how you are feeling and if you are feeling unwell if you would like to proceed. Thus, any complication will be promptly identified and addressed.

Thus, the study design excludes patients at risk of complications due to DSE. Careful monitoring during the procedure mitigates the small risk associated with it.

The risks related to the procedure will be explained to you by your treating doctor during the consent process.

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

Sometimes during the course of a research project, new information becomes available about the condition 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.

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

While you are participating in this research project, you will receive advice about the medications or treatments you have been taking for your condition or for other reasons. 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.

**11 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. A member of the research team will inform you if there are any special requirements linked to withdrawing.

If you do withdraw 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.

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

The likelihood of this research project stopping unexpectedly is very low; however, if it is stopped, you will be notified.

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

Your treating team will be provided with a summary of the collective results once the data we collect have been analysed.

If the individual study results are normal, they will be sent by mail to the study participants. If abnormal, it will be discussed by the study team in person along with appropriate explanation and recommendations.

Results of the entire study may not be available until about 6 months after the study finishes. They will be provided to you if you wish.

Your engagement with the treating team will continue as indicated by your clinical condition even after the study finishes.

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

**14 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. Any information about you that is sent out of the hospital will have a code and will not show your name or address, or any information that directly identifies you. 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 their 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 these health records if they are relevant to participation in this research project.

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. This information will be anonymous. This means that the information will not include any details about you, and your identity will not be made available.

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

In accordance with relevant Australian and/or South Australia privacy and other relevant laws, you have the right to request access to your information collected and stored by the study 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 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.

**15 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 for the participant. If you are eligible for Medicare, they can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital. You also have the right to seek compensation through the legal system.

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

This research project is being coordinated by Dr. Jeyamani Ramachandran at Flinders Medical Centre. This study does not have any external funding. All clinical information connected with this study will be owned by these sites. No member of the research team will receive a personal financial benefit from the participant’s involvement in this research project (other than their ordinary wages).

**17 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. The ethical aspects of this research project have been approved by the Southern Adelaide Clinical Human Research Ethics Committee. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research* (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

**18 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 on *[phone number]* or any of the following people:

**Clinical contact person 1**

|  |  |
| --- | --- |
| Name |  |
| Position |  |
| Telephone |  |
| E-mail |  |

**Clinical contact person 2**

|  |  |
| --- | --- |
| Name |  |
| Position |  |
| Telephone |  |
| E-mail |  |

**Clinical contact person 3**

|  |  |
| --- | --- |
| Name |  |
| Position |  |
| Telephone |  |
| E-mail |  |

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

**Local site contact person**

|  |  |
| --- | --- |
| Name |  |
| Position |  |
| Telephone |  |
| E-mail |  |

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:

**Complaints contact person**

|  |  |
| --- | --- |
| Name |  |
| Position |  |
| Telephone |  |
| E-mail |  |

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

|  |  |
| --- | --- |
| Reviewing HREC name | Southern Adelaide Clinical HREC |
| Position | Executive Officer |
| Telephone | (08) 8204 6453 |
| Email | Health.SALHNOfficeforResearch@sa.gov.au |

**Consent Form –** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | Evaluation for cirrhotic cardiomyopathy:  A prospective study of global cardiac function in decompensated cirrhosis and its clinical significance |
| **Short Title** | Cirrhotic cardiomyopathy study |
| **Project Sponsor** | Flinders Medical Centre, SA |
| **Coordinating Principal Investigator** | Dr.Jeyamani Ramachandran |
| **Site Principal Investigator** | *[Principal Investigator]* |
| **Location** | *[Location where the research will be conducted]* |

**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 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 project without affecting my future health care.
* I understand that I will be given a signed copy of this document to keep.
* I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Flinders Medical Centreconcerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.
* I understand that, if I decide to discontinue the research project 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.

Name of Participant (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**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) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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†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*

|  |  |
| --- | --- |
| **Title** | Evaluation for cirrhotic cardiomyopathy:  A prospective study of global cardiac function in decompensated cirrhosis and its clinical significance |
| **Short Title** | Cirrhotic cardiomyopathy study |
| **Project Sponsor** | Flinders Medical Centre, SA |
| **Coordinating Principal Investigator** | Dr.Jeyamani Ramachandran |
| **Site Principal Investigator** | *[Principal Investigator]* |
| **Location** | *[Location where the research will be conducted]* |

**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 *[Institution]*.

Name of Participant (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

**Declaration by Study 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.