Participant Information Sheet & Consent Form

Adult providing own consent

Title	Load Incorporating Cardiac Assessment by Echocardiography in Patients with Sepsis: Prospective Observational Study
Short Title	LIAISE study
HREC number	*EC00172*
Coordinating Principal Investigator	Prof. John Fraser
Location	The Prince Charles Hospital

Part 1 What does my participation involve?

1 Introduction

As the participant, you are invited to participate in the LIAISE study investigating the best way to diagnose heart problems associated with sepsis. The study has been approved by a Human Research Ethics Committee.

This information sheet and consent form tells you about the research project. It explains why the study is being run and what participation would involve. Knowing what is involved will help you to decide whether or not you want to take part in the research.

Please read this information carefully. Ask questions about anything you don't understand or want to know more about. Before deciding whether or not to take part in this research, you might want to talk about it with a relative, or friend. Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you to take part.

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

- Understand what you have read / what has been explained to you
- Consent to take part in the research project
- Consent to use of your personal and health information as described.

You will be given a copy of this information sheet and consent form to keep.

2 What is the purpose of this research?

Ultrasound is commonly used in hospitals as part of patient examination. An ultrasound machine use sound waves to examine internal body structures, including the heart. It is a non-invasive, pain-free, and safe assessment tool.

The LIAISE study is comparing a new ultrasound approach for evaluating heart function in patients with sepsis compared to conventional ultrasound parameters. Sepsis is an infection of the blood and causes inflammation in the entire body and it potentially causes damage to many organs, including the heart (known as septic cardiomyopathy (SC)).

Currently, the heart assessment in sepsis is mainly conducted by ultrasound, also called "echocardiography", but assessment of the heart in sepsis is difficult. This is because blood pressure and the amount of circulating blood change in sepsis, and current heart assessment methods are significantly affected by these changes and cannot capture accurate heart function.

To get more accurate heart function, a new echocardiography technique is being explored, called "load-incorporating echocardiography". It can take into account these changes in patient's blood pressure and blood volume and potentially capture more accurate heart function in sepsis.

In this project, we are comparing this new echocardiographic technique to current heart assessment at The Prince Charles Hospital Intensive Care Unit (Queensland, Australia), Queen Mary Hospital (Hong Kong), Cape Town University (South Africa), and Toronto General Hospital (Canada). This project is led by Prof. John Fraser from the Critical Care Research Group at The Prince Charles Hospital, and Dr. Maithri Siriwardena in The Prince Charles Hospital. The study results will also be presented as part of a research higher degree by a member of the study team.

3 What does participation in this research involve?

If you agree to participate in this study, you will be asked to sign the Participant Consent Form.

This study involves the collection of your health information and echocardiography data as below.

1. **Collection of medical chart data on your background, treatment, and progress after discharge.**
2. **Additional analysis of your echocardiography data to examine new echocardiography parameters.**
3. **Blood sampling for the basic analysis of heart damage and infection severity.**
4. **15-minute telephone interviews at 1 year after your ICU admission.**

Please note: you will receive regular treatment as determined by your treating doctor irrespective of project participation. This study collects your health data and echocardiography data, and after the 1-year telephone interview, the study ends and no further follow-up is required from you. There are no additional costs associated with participating in this research.

Specifically, the research staff will collect the data on your health history and treatment content from your medical records. This data will include your age, weight, gender, race, hospital admission diagnosis, previous and current health conditions, the previously available echocardiographic data, and readmission diagnosis.

During admission, you will receive one or two echocardiography examinations and at leaset one blood collectionas per regular clinical practices to exclude undetected heart diseases. Thereafter, we will analyse the collected data at

the echocardiography and laboratory lab for new echocardiography parameters and basic heart and infection assessments.

In the telephone interview for outcome data collection, you or your nominated relative/friend will be asked a few questions whether you have been admitted to any hospitals since your discharge.

If you have any concerns about the study, you are encouraged to raise these with the research team or the nurse or doctor looking after you.

4 What do I have to do?

We will follow up by phone 1 year after your ICU admission to check on your progress, so please let us know if you have been readmitted to hospital for any reason at that telephone interviews. There are no other things specific you need to do in order to participate in the study. All of the assessments will be carried out by investigators, doctors, or the nurses looking after you.

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

The potential risk of participating in this research is the negligible chance of leakage of your information during the data collection or echocardiography analysis process. This means there is a very small chance that your personal or medical information could be accessed by someone who is not authorized or not related to this research. However, all data, including echocardiography results, will be extracted without your name or any other identifiers and stored in a password-protected cloud database owned by The University of Queensland, accessible only by designated staff. Only authorized study members have access to this database to minimize the risk of data leakage.

6 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team. This notice will allow the research team to prepare for your withdrawal. If you do withdraw your consent during the research project, the research team will not collect additional 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 research team up to the time you withdraw will form part of the research project results. If you would not like the research team to retain your data, please advise a member of the research team at the point of consent and you will not be included in this study.

7 What happens when the research project ends?

After the 1-year telephone interview, the study ends and there is no further follow up required. Your de-identified data will be used for LIAISE study analysis if you agree to participate in this study by signing this consent form.

Part 2 How is the research project bring conducted?

8 What will happened to information about me?

By signing the consent form you consent to the research team to collect and use personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Information about you will be kept on a password-protected computer and in a locked filing cabinet, and will only be made available to members of the research team. Your information will only be used for the purpose of this research project and will only be disclosed with your permission, except as required by law.

Information about you will 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 research team continuing to access 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 data) by the relevant authorities and authorised representatives of the coordinating centre, The University of Queensland, the institution relevant to this participant information sheet, or as required by law. By signing the consent form, you authorise the 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. Your data will be reported/presented in a de-identified format combined with the rest of the study data.

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

In accordance with relevant Australian and/or Queensland 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 to 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 in a password-protected cloud database accessible only by designated staff. It will be disclosed only with your permission, or as required by law.

9 Complaints

If you experience any issues as a result of this research project, please contact the study team as soon as possible, and we will assist you in addressing the problem.

10 Who is organising and funding the research?

This research project is being conducted by Professor John Fraser, Director of the Critical Care Research Group (https://www.ccrg.org.au/) at The Prince Charles Hospital and sponsored by The University of Queensland.

11 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 HREC (EC00172)

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2018). This statement has been developed to protect the interests of people who agree to participate in human research studies.

12 Further information and who to contact

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

If you would like any further information concerning this project or if you have any medical problems which may be related to your involvement in the project or if you have any complaints, you can contact the coordinating research group (Critical Care Research Group) on 07 3139 6880 or any of the following people:

Clinical contact person

Name	Siriwardena Maithri
Position	Intensivist and cardiologist in The Prince Charles Hospital
Telephone	(07) 3139 4000
Email	Maithri.Siriwardena@health.qld.gov.au

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

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	**Metro North Health HREC**
Telephone	**07 3646 5280**
Email	MetroNorthResearch-Ethics@health.qld.gov.au

Complaints contact person

Position	Metro North Health Research Governance Manager
Telephone	**07 3647 9550**
Email	MetroNorthResearch-RGO@health.qld.gov.au

Consent Form

Adult providing own consent

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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 care.
- I understand that the data collected by the research team will have identifiable information removed and be entered into a secure database at The Prince Charles Hospital.
- I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by 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 Researcher[†] (please print)

_____

Signature _____ Date _____ Time

[†] An appropriately qualified 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

Best Contact for 1 Year Follow-Up:

Self or Other (Relationship:) / Contact number:

Form for Withdrawal of Participation

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Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine care, or relationships with those treating me or relationship with researchers, The Prince Charles Hospital.

Name of Participant (please print) _____

Signature of Person providing consent _____ Date _____

Permission to use data collected up to the date of withdrawal: Yes ☐ No ☐

In the event that the participant's decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

Declaration by 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 Researcher (please print) [†] _____

Signature _____ Date _____

[†] An appropriately qualified member of the research team must provide information concerning withdrawal from the research project.

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