Participant Information Sheet/Consent Form

Royal Brisbane and Women's Hospital

Protocol Title:	Safety and useability of a novel robot-assisted echocardiographic examination.
Protocol Number:	RMI-ROBOTECHO-CIP-002_V02_20240813
HREC Reference:	109986
Project Sponsor:	Mr. Mathew Saliba CEO, RMI Oceania Pty. Ltd.
Principal Investigator:	Prof John Atherton Director of Cardiology and Senior Staff Cardiologist, Cardiology Royal Brisbane and Women's Hospital rbwh-cardiology-dso@health.qld.gov.au
Associate Investigator:	Dr Adam Scott Director of Cardiac Sciences, Cardiac Investigations Royal Brisbane and Women's Hospital
Location:	Cardiac Investigations Unit Royal Brisbane and Women's Hospital

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you are being investigated for cardiac disease and will already have had a standard ultrasound performed. The research project is testing a new medical device to conduct a cardiac echocardiogram (ultrasound) and compare its use to that of the existing (standard of care) ultrasound.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and 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 don't understand or want to know more about. Before deciding whether to take part, you might want to talk about it with a relative, friend or your local doctor.

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

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to have the test that is 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?

This research is to investigate the ability of sonographers to perform cardiac ultrasound (echocardiogram or 'echo') examinations via controlling an ultrasound probe using a robotic arm. This will help specialised healthcare staff in metropolitan areas to perform advanced ultrasound assessments on patients in rural and remote areas without requiring these staff or these patients to travel great distances to perform such examinations.

The research will contribute to information to help decide whether the robotic ultrasound can replace the conventional (manual) ultrasound procedure, especially in remote areas.

The robotic device is described as investigational (still in the experimental phase) and, therefore, is not an approved device in any country for routine use.

This research is being conducted and sponsored in Australia by RMI Oceania.

3 What does participation in this research involve?

You have been selected as a possible research participant because you are being investigated for cardiac disease.

Prior to any research-specific procedures you will have discussed this Participant Information Sheet with the study team and if needed other healthcare professionals or family. If you agree to participate you will sign this consent form.

The study team will decide whether you are eligible to participate. This will involve providing some medical and demographic information (which is routine). Importantly you will need to already have had a clinical (routine) cardiac ultrasound performed. Information from this routine cardiac ultrasound will guide your clinical treatment plan.

You will undergo a second cardiac ultrasound for research purposes which is operated robotically. This ultrasound is performed using a robotic arm that holds the ultrasound probe. This differs from routine practice where the sonographer holds the probe. The sonographer will guide (not hold) the probe using the robotic arm. The sonographer will be co-located within the same examination room as you (but not at your bedside like the manual scan). They will be controlling the robotic arm from a console. A second sonographer will be at your bedside to ensure that you are always safe and intervene should it be necessary. The robotically controlled ultrasound can be stopped at any time should you feel uncomfortable. An example of the robotic ultrasound setup is shown in Figure 1 below.

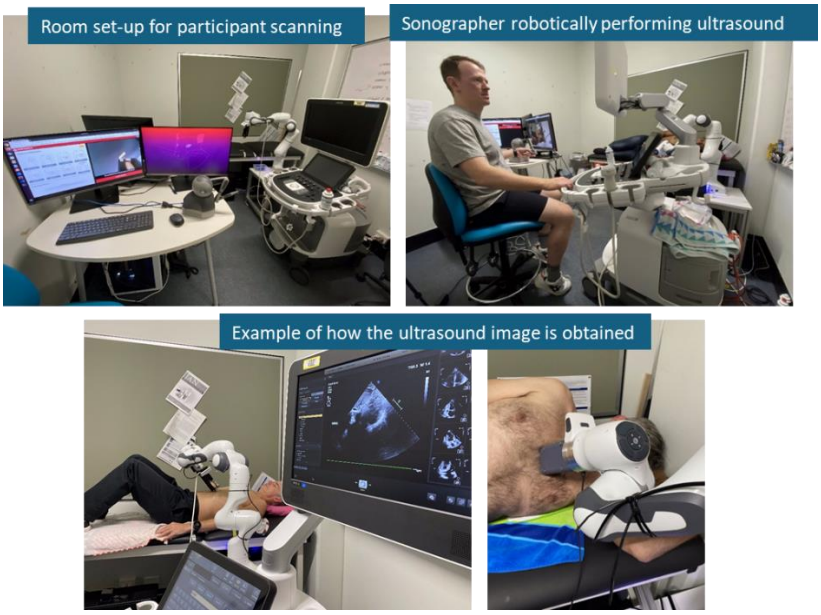

***Figure 1**: Robotic ultrasound assistance tool (RUAT system and participant volunteer cardiac scan.*

No clinical decisions will be made from the images provided by the experimental (robot-assisted) ultrasound.

Your time commitment for this ultrasound is approximately 30-60 minutes. You will then be asked to complete a short survey of your experience to provide feedback on your impressions of the technology and service compared to your routine ultrasound.
Your total time commitment will not exceed 90 minutes. There are no follow up visits required for this research, however, you will be contacted on the ward if an inpatient or by telephone if an outpatient within 72 hours of the scan for safety follow up. Your involvement ends at the completion of the follow up consult. The only exception is if you experience any adverse effects from the procedure when follow up after 72 hours is required.

The research project will be monitored by the research investigator/s, the research ethics committee and representatives of the sponsor team to ensure that it is being conducted in accordance with Good Clinical Practice.

There are no additional costs associated with participating in this research project, nor will you be paid.

You will be excluded from participating in the research if:

- You are under 18 years of age.
- Pregnant.
- Unable to provide Informed Consent.
- Have poor mobility or are acutely symptomatic.

4 What do I have to do?

To participate in this research project, you will not be required to make any changes to your current treatment.

The robotically assisted echocardiogram will be undertaken as soon as practically possible f after providing informed consent , to ensure your time commitment is reasonable.

Your commitment to the research ends at the completion of the safety follow up consult which is no more than 72 hours post echocardiogram. You will not have any further responsibilities associated with participating in this research.

5 Other relevant information about the research project

Research on the safety, use, and functionality of the robotically controlled ultrasound has previously been conducted by the research sponsor. This is an additional research project to supplement data already available.

Data from this research will inform further research projects comparing the robotically controlled ultrasound with the standard (manual) procedure, particularly in remote locations. Data from all these research projects will be used to seek regulatory approval to use the robotically controlled ultrasound.

This study is being performed at the Royal Brisbane and Women's Hospital, with no collaborating organisations or staff outside of this hospital.

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 your treating healthcare providers.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. Refusal to participate will not affect ongoing care.

Since this research project only involves an additional robotically controlled ultrasound to the standard (manual) ultrasound already performed, there is no clinical requirement for an alternative procedure. The only decision you will need to discuss with your healthcare provider is whether you wish to participate in this research.

8 What are the possible benefits of taking part?

The research will not be of personal benefit to you, but the information collected may contribute to future research and regulatory approval of this device.

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

The robotically controlled ultrasound will perform a series of automated and sonographer-controlled movements during the procedure. The automated movements are to assist the sonographer in putting the robot into a good position near your chest before the sonographer takes control of the robot to place the ultrasound probe on your chest. The automatic movements are at a slow speed, and the sonographer-controlled speed is very slow.

The robotic arm has a sensor which ensures that the robot does not push too hard on the chest. This sensor is tested every day to ensure it performs properly. The cardiac sonographer who guides the robot is not at your bedside but is located within the same examination room as you and can stop the robot immediately if you feel any discomfort. In addition, there is a second sonographer sitting at your bedside who will always ensure your safety and comfort.

You will also hold an emergency stop button which may be used to stop the robot at any time during your examination.

You may find some discomfort with the probe being pressed on your chest. If you feel discomfort during the procedure, please immediately advise the operator. The robot arm is limited in how hard it is allowed to press on your chest and presses more softly than when the operator holds the probe in their hand. Again, even when the robot is holding the probe, please advise the operator immediately if you feel discomfort.

As this procedure is experimental, images acquired using the experimental device are not used for clinical management. The images obtained from the routine (manual) ultrasound will guide your treatment options.

The possible risks associated with participating in this study include discomfort and possibly an adverse effect (such as pain or bruising) if the robotic arm pressed too hard on your chest. The probability of such an adverse effect is uncommon and the pain/bruising should only last a short time. You should advise the sonographer and/or research investigator immediately if this occurs to decide whether you should need any treatment (e.g., pain medication).

10 What if new information arises during this research project?

Sometimes during a research project, new information becomes available about the experimental device and/or procedure that is being studied. If this happens, your study team will tell you about it and discuss with you whether you want to continue in the research project.

This will only affect you between the time of consent and receiving the experimental ultrasound.

You would then sign a withdrawal of consent form.

11 Can I have other treatments during this research project?

Participating in this research project will not require you changing your clinical treatment plan, nor will you be required to change any medications or treatments.

12 What if I withdraw from this research project?

You have the right to refuse to participate or withdraw from this study at any time without affecting in any way your clinical care or treatment at the RBWH. If you decide to withdraw from the study after research data has already been collected, you will be communicated with by an investigator if you consent to the data to be collected and collated. If you choose to withdraw, with no access to subsequent data collection or collation, then this research data will be immediately destroyed as per Queensland Health and RBWH policy and procedures. Please do not hesitate to **call or email the Study Co-ordinator Dr Kristyan Guppy-Coles (0438758378; Kristyan.Guppy-Coles@health.qld.gov.au**) if you choose to withdraw from the study

14 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:
• Unacceptable side effects
• The experimental device not functioning as intended
• Decisions made in the commercial interests of the sponsor or by local regulatory/health authorities**.**

15 What happens when the research project ends?

This research project does not involve any treatment or medications. In addition, it only involves the use of an experimental device for a short period of time during the research. No further use of this or other experimental devices is required when the project ends.

The research investigator will provide a summary of the research results once the Sponsor has completed review of all the data collected. This may take several months after the completion of the research. The Sponsor will advise the Investigator when the results are available.

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.

All data that is identifiable can only be reviewed by the research project staff, representatives of the ethics committee, regulatory authorities and Sponsor staff required to monitor the research. All staff are bound by the Privacy Laws, Good Clinical Practice, Queensland Health legislation and the Australian Code for the Responsible Conduct of Research.

Identifiable data may include your routine health/medical records that are stored in the hospital electronic data management system and are accessible only to hospital staff or your healthcare providers with password protection.

For the study the following health (and personal) information will be collected and only used to aid in determining inclusion/exclusion from the study, inform safe and effective use of ultrasound, and for safety follow-up contact with you.

- Age (date of birth), gender, heigh, weight

- General medical history if relevant, i.e., symptoms or diagnosis relevant to undergoing an echocardiogram
- Personal contact details: phone number, email address, residential address

The Investigational site will retain a list of research participants which will include some personal details. Any identifiable participant information recorded on paper will be either stored in the medical records department or in locked cabinets only accessible to researchers involved in this project.

Except for the above, no data or information you provide as part of your participation in this research will be individually identifiable to anyone apart from the research team's RBWH investigators. The investigational site will transcribe or enter confidential information from medical records into case record forms or electronic databases. The details on the case record forms or in the databases are deidentified and only re-identifiable back to your confidential information using a unique participant identifier by the research staff.

The Sponsor (RMI Oceania) will not be provided with any confidential information from or associated with participant examinations, only anonymised research reports.

The robotic arm system contains a webcam that is used for the physically co-located sonographer to be able to better watch the robot's movements through a computer monitor within the same room. This webcam is only linked to that monitor and is not connected to any network, the internet or any other connection outside the room. The video streaming from the webcam is live and is not recorded.

By signing this 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 authorised representatives of the Sponsor (RMI Oceania), the Investigational site or ethics committee, or as required by law.
- You authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.
- That information related to your participation in this research may be recorded in your health records.

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. Any individual participant data will only be described using the unique research identifier that does not contain any confidential information.

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 be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Data storage, access and destruction

Hard copy (research-specific) data will be stored by the Site (RBWH Cardiology) in a locked cabinet in a secure location, only accessible to the RBWH research trial team and the Sponsor's monitor and only accessed as needed. Electronic data (deidentified, non-re-identifiable) will be securely stored on QH asset PC workstations in secure digital folders with access only by the

RBWH research trial team and the sponsor's assigned trial monitor. Participant data entered into electronic case report forms and transferred to the Sponsor's study-specific database is deidentified and only accessible to the Sponsor's assigned data manager/s through strictly controlled 21 CFR 11 (signature traceability) compliant databases.

Data will be stored according to "The Australian Code for the Responsible Conduct of Research, Section 2.1.1".

Data will be kept for 15 years after the completion of the study, in accordance with the requirements of Health Privacy Principals and ICH GCP. Data will be disposed of after the completion of the study according to "The Australian Code for the Responsible Conduct of Research, Section 2". Hardcopies will be disposed of via a confidential shredding process. For electronic data, software which permanently erases data will be used to destroy records. Records will not be destroyed without the written consent of the Principal Investigator and Study Sponsor.

Information from the study may be published. All study participant data shall be deidentified (not re- identifiable) and described as aggregated data.

Once the clinical trial is completed the research team would like to share with you a layperson summary of the study results. If you wish to receive this information, you are asked to agree via the participant survey at the completion of the echocardiogram. You will be asked for your email address for this communication. Your email address will not be used for any other purpose.

17 Complaints and compensation

If you suffer any injuries or complications because 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.

There are two avenues that may be available to you for seeking compensation if you suffer an injury because of your participation in this research project:

• The Medical Technology Association of Australia (MTAA) has set up a compensation process, with which the Sponsor (RMI Oceania) of this research project has agreed to comply. Details of the process and conditions are set out in the *MTAA Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Clinical Trial*. In accordance with these Guidelines, the sponsor will determine whether to pay compensation to you, and, if so, how much. A copy of the Guidelines is available to you from the research staff on request. If you have any questions about the Guidelines, please the Metro North Hospital and Health Services Research Governance Manager, Metro North Office of Research (0736479550), MetroNorthResearch-RGO@health.qld.gov.au.

• You may be able to seek compensation through the courts.

18 Who is organising and funding the research?

This research project is being conducted, sponsored and funded by RMI Oceania.

RMI Oceania may benefit financially from this research project if, for example, the project assists RMI Oceania to obtain approval for the experimental, robotically controlled arm to conduct a cardiac ultrasound.

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

Apart from their usual wages, the members of the research team will receive no personal direct payment from your involvement in this research project. Furthermore, with the exception of Dr Adam Scott (see conflict of interest statement below), no other member of the research team will benefit financially from this medical device.

Conflict of Interest Statement:
Dr Adam Scott, Director of Cardiac Sciences, Cardiac Investigations Unit, Royal Brisbane and Women's Hospital is a co-investigator of the study and declares a conflict of interest (COI). Dr Scott is a Director, and shareholder of the Sponsor company RMI Oceania Pty Ltd with financial and intellectual property interests.
Dr Scott has contributed intellectually to the design of both the medical device and the clinical trial.

To manage the COI Dr Scott will not:

- Be involved in identification of patient participants,
- Consent patients for the study,
- Conduct robot-assisted scans or standard manual echo scans,
- Have contact with the patient participants,
- Record or access clinical study data during the trial,
- Record or review safety events.

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 Gold Coast Hospital and Health Service Human Research Ethics Committee.

Approval has also been given by the Royal Brisbane and Women's Hospital Research Governance.

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 **Professor John Atherton** on [**07 3646 3257**] or any of the following people:

Clinical contact person/s

Name	**Professor John Atherton (**medical contact)**
Position	Principal Investigator, Director of Cardiology Cardiology Royal Brisbane and Women's Hospital
Telephone	(07) 3646 3257
Email	rbwh-cardiology-dso@health.qld.gov.au
Name	**Kristyan Guppy-Coles**
Position	Study Co-ordinator Cardiac Investigations Unit Royal Brisbane and Women's Hospital
Telephone	0438 758 378
Email	kristyan.guppy-coles@health.qld.gov.au

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

Complaints contact person

Name	Research Governance Manager
Position	Research Governance Manager- Metro North Hospital and Health Services (MNHHS), Metro North Office of Research,
Telephone	07 3647 9550
Email	MetroNorthResearch-RGO@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	*Gold Coast Human Research Ethics Committee*
	Office for Research Governance and Development
HREC Executive Officer	*GCHHS HREC Coordinator*
Telephone	(07) 56873879
Email	GCHEthics@health.qld.gov.au
HREC Reference number:	109986

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

Name	Research Governance Manager
Position	Research Governance Manager- Metro North Hospital and Health Services (MNHHS), Metro North Office of Research,
Telephone	07 3647 9550
Email	MetroNorthResearch-RGO@health.qld.gov.au

Consent Form

Protocol Title: Safety and useability of a novel robot-assisted echocardiographic examination.

Protocol Number: RMI-ROBOTECHO-CIP-002 V02
HREC Reference: 109886
Project Sponsor: Mr. Mathew Saliba
CEO, RMI Oceania Pty. Ltd.

Principal Investigator: Prof John Atherton
Director of Cardiology and Senior Staff Cardiologist, Cardiology Department, Royal Brisbane and Women's Hospital
rbwh-cardiology-dso@health.qld.gov.au

Associate Investigator: Dr Adam Scott
Director of Cardiac Sciences, Cardiac Investigations
Royal Brisbane and Women's Hospital

Location: Cardiac Investigations Unit
Royal Brisbane and Women's Hospital

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 Royal Brisbane and Women's Hospital concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

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 Co-ordinator/Sonographer 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 Co-ordinator/
Sonographer Researcher†
(please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Form for Withdrawal of Participation

Protocol Title: Safety and useability of a novel robot-assisted echocardiographic examination.

Protocol Number: RMI-ROBOTECHO-CIP-002 V02

HREC Reference: 109886

Project Sponsor: Mr. Mathew Saliba
CEO, RMI Oceania Pty. Ltd.

Principal Investigator: Prof John Atherton
Director of Cardiology and Senior Staff Cardiologist, Cardiology Department, Royal Brisbane and Women's Hospital
rbwh-cardiology-dso@health.qld.gov.au

Associate Investigator: Dr Adam Scott
Director of Cardiac Sciences, Cardiac Investigations
Royal Brisbane and Women's Hospital

Location: Cardiac Investigations Unit
Royal Brisbane and Women's Hospital

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 Royal Brisbane and Women's Hospital.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Co-ordinator/Sonographer Researcher will need to provide a description of the circumstances below.

Declaration by Study Co-ordinator/Sonographer 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 Co-ordinator/ Sonographer 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.