**Participant Information Sheet and Consent Form**

Protocol Name

# Intravascular Lithotripsy Catheter Balloon for Calcified Coronary Artery Pilot Study.

Investigators

Dr Michael Zhang

Dr Pyi Naing

Matthew Hiskens, PhD

**1. Introduction**

You are invited to take part in this research project at the Mackay Base Hospital Cardiac Catheterisation Laboratory. You have been invited to participate as you will require percutaneous coronary intervention (PCI) to assist with the placement of stents in your heart, in line with Australian guidelines.

This information sheet/consent form tells you about the research project. It will explain the process involved in the procedure. Knowing what is involved will help you decide if you wish to take part in the research.

Please read the information carefully. Ask questions about anything that you don’t understand or want to know more about.

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 regardless of whether you take part.

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

* Understand what you have read
* Consent to take part in the research study
* Consent to the use of your personal 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?**

The purpose of this study is to trial a new form of PCI. Calcium build-up in the arteries of your heart makes the stenting procedure more difficult and less effective. Current methods of PCI involve inflating a cutting balloon or laser to clear calcium in the artery. A new method called Intravascular Lithotripsy (IVL) involves a variation on this concept, with a new balloon using soundwaves to clear the calcium build-up. The new soundwave balloon device is known as Shockwave IVL, and large international studies have shown that this method is safe and effective compared to alternative strategies. Research in Australia is required for approval of the device by the Therapeutic Goods Administration (TGA) of Australia, and research is still underway to determine the durability of the device.

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

All participants will have the procedure completed by an investigator who is trained in using the Shockwave IVL. Participating in this research involves the insertion of the IVL catheter and the inflation of the IVL balloon, in a similar way to other forms of PCI that you would receive. Following this, soundwave pulses will be delivered through the IVL balloon. The stent will then be implanted as is usual.

Following this procedure, all care will be the same as usual.

Participation in this research project is entirely voluntary. The consent form must be signed prior to any study assessments being performed.

**4. What are the possible benefits in taking part?**

By taking part in this project, you may be helping demonstrate the safety and effectiveness of coronary IVL in assisting stent implantation in severely calcified coronary arteries.

A benefit of this study is showing the ability to provide IVL to Mackay Base Hospital patients. This may lower the risk of major adverse cardiac events seen in patients with severe coronary calcification and may reduce the need for patients to be transferred to tertiary centres for high risk procedures.

**5. What are the possible risks and disadvantages in taking part?**

There are no possible risks or disadvantages in taking part in this research.

**6. What will happen to your information?**

Information about you will be de-identified by replacing your name and identifying details with a Personal Identification Number (PIN). In this way, no information about you will be able to be tracked by anyone outside of the study. To further ensure confidentiality, your de-identified information will be kept on a password protected computer available only to the investigators.

After the study is completed, your de-identified information will be kept on a password protected computer for fifteen years, at which point the data will be destroyed or deleted.

Once the study is completed you have the option of receiving a summary of study results from the Department of Cardiology and the option of requesting a copy of the final peer reviewed journal paper.

**7. What if you want to withdraw from this research project?**

You can withdraw from the research project at any point. Your care will not be disadvantaged in any way if you withdraw from the project. Data that has already been collected up until your withdrawal will still be securely stored for fifteen years, but no further data will be collected, and you will not receive any further communication about the study.

**8. Complaints**

Complaints should be directed to the Department of Cardiology, Mackay Base Hospital as per the Queensland Health Complaints guidelines.

For more information, visit <https://www.qld.gov.au/health/contacts/complaints>

**9. Who has reviewed the research project?**

The research project has been reviewed by the Department of Cardiology at Mackay Base Hospital, as well as The Townsville Hospital Human Research Ethics Committee.

**10. Further information and who to contact?**

This project has been reviewed and approved by the Townsville Hospital and Health Service Human Research Ethics Committee. For concerns relating the conduct of this project contact the Chairperson on Phone: 07 4433 1440 or Email: TSV-Ethics-Committee@health.qld.gov.au.

If you would like more information on this project please contact Dr Michael Zhang, who is the Research Contact Person and Director of Cardiology on Phone: 07 4885 7953 or Email: Michael.zhang@health.qld.gov.au

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**By signing this form, you agree that:**

1. The nature and purpose of the research project has been explained to me. I understand it and acknowledge that taking part in the study is voluntary.
2. I have been given an information sheet which explains the purpose of the study, the possible benefits and the possible risks.
3. I understand that I may not directly benefit from taking part in the trial.
4. I understand that, while information gained during the study may be published, I will not be identified, and my personal results will remain confidential.
5. I understand that I can withdraw from the study at any stage and that it will not affect my medical care, now or in the future.

**NAME OF PARTICIPANT:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SIGNATURE:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**DATE:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**By signing this form, I certify that:**

1. I have explained the study to the participant/volunteer and consider that he/she understands what is involved

**NAME OF STAFF MEMBER:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SIGNATURE:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­\_

**DATE:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_