



## EXPLANATORY STATEMENT

(Healthy Participant Group)

**Project ID: 32631**

**Project title: Development of Clinical Utility for Point of Care MRI (PoCeMR)**

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You are invited to take part in this study. Please read this Explanatory Statement in full before deciding whether or not to participate in this research. If you would like further information regarding any aspect of this project, you are encouraged to contact the researchers via the phone numbers or email addresses listed above.

### What does the research involve?

Magnetic resonance imaging (MRI) is one of the most important medical imaging technologies used worldwide. It is non-invasive and does not include exposure to ionising radiation. MRI can provide an image of the internal structure of the body by utilizing the inherent composition of the human body (more than 70% water).

In low-field MRI, imaging is performed at ultra-low field strengths (less than 0.1 Tesla) for point of care applications, in which portability and cost-effectiveness are crucial factors. PoCeMR is one such MRI scanner that will be used to acquire images of the brain.

On the other hand, portable point of care medical devices have revolutionised the way in which people receive medical imaging. They can bring timely and adequate diagnostics to people in need but also open up the opportunity to address the healthcare inequality in the rural and remote areas.

Low-cost and point of care MRI scanners (PoCeMR) are poised to expand the accessibility to MRI scans and provide timely point-of-care for patients in remote areas. However, due to the ultra-low magnetic field strength employed in the portable MRI technology, the resulting image quality is significantly inferior compared to the current generation high strength magnetic field scanners, e.g. the signal to noise ratio in portable scanners is only 2% of higher strength 3 Tesla MRIs. Furthermore, the clinical utility of portable MRIs is not fully explored at this stage. This project will target the image quality issue of the PoCeMR scanners and test their clinical utility with datasets acquired from radiology practices.

This project will develop artificial intelligence (AI) based image reconstruction and post-processing methods for the point of care portable MRI scanners, and validate the developed methods using datasets from healthy participants.

There are two main aims in this project:

- (i) Developing AI models to improve image quality in the Point of Care MRI (PoCeMR) scanners, and
- (ii) Investigating their clinical utility in healthy subjects.

In this study, you will undergo two MRI scans of your brain: the first one will be using the 3T MRI scanner (no more than 30 minutes) , and the second one using the low-field PoCeMR (approximately 45 minutes). The scanning day will be determined at a time suitable for you and the scans will be done at Monash Biomedical Imaging.

On the day of your scan and prior to scanning, you will be screened by a radiographer to make sure you are eligible for an MRI scan. Only one screening needs to be done for each participant as principles of MRI safety are the same between the 3T and PoCeMR scanners.

During the MRI scan, whether in the 3T scanner or the PoCeMR, you will lie on a bed while the radiographer is operating the scanner. You won't be asked to do anything; just to rest and keep still as much as possible.

Once the scans are finished, you are free to leave MBI.

### **Why were you invited for this research?**

You have been invited to participate in this study because (a) you responded to our advertisement and are willing to take part in our study and (b) you were the participant of a prior study at Monash Biomedical Imaging and had previously consented to being contacted for participating in future research projects..

### **You can withdraw from the study**

Being in this study is voluntary and you are under no obligation to consent to take part. However, if you do consent to participate, you may withdraw from further participation at any stage, but you will only be able to withdraw data prior to the publication of the report of the project. Withdrawal of data will not be possible 4 weeks after the MRI scans.

### **What are the benefits and potential risks or inconveniences?**

The community benefits include (i) the reduced total cost for medical examinations using MRI, and (ii) improved healthcare equality for the rural and remote communities.

There are no known risks to short term exposure to MRI for you. You may experience annoyance due to the acoustic noises generated by the PoCeMR or 3T MRI scanners, however, you will be provided with earplugs to reduce this disturbance.

You might also experience feelings of boredom or being closed in, when in the scanner. The radiographer is monitoring you constantly and you can inform them of your discomfort using a distress buzzer or directly talking to them.

For all MRI images acquired at MBI, a qualified radiologist will examine the images. In the unlikely case of incidental findings that require medical follow-up, you will be contacted if you have consented to do so, using the information you have provided on your consent form.

### **How will this information be stored and protected?**

Information collected will be stored in accordance with Monash University regulations and kept on University premises. All records will be kept in locked filing cabinets or in password-protected computer files indefinitely. Results of the research will be published as group statistics and reports and will not identify you in any way.

In accordance with data sharing guidelines, de-identified data may be made available for use by the other researchers and collaborators as well as for commercial product development. This data will be held in secure public repositories and may be a requirement of some journals prior to publication. Any shared data will not include your identifying details.

### **How will the information you give for the study be kept private?**

Your health data will not be passed to anyone. The information about you collected for the study will be kept strictly confidential. Only the researchers and their staff will have access to the information. You will not be identifiable in any documents published about the study.

When the collected data is no longer required, they will be permanently deleted.

### **Counselling Services if Adversely Affected**

- Trained first-aiders at MBI at all times

### **Complaints**

Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the Executive Officer, Monash University Human Research Ethics Committee (MUHREC):

Executive Officer  
Monash University Human Research Ethics Committee (MUHREC)  
Room 111, Chancellery Building D,  
26 Sports Walk, Clayton Campus  
Research Office  
Monash University VIC 3800

Tel: +61 3 9905 2052      Email: [muhrec@monash.edu](mailto:muhrec@monash.edu)      Fax: +61 3 9905 3831

Thank you,

**(insert Chief Investigator's signature)**

**Dr. Zhaolin Chen**

