

Participant Information Sheet

Healthy Volunteers: 7T

Study Title: Image Optimisation for MRI Research Studies

You are being asked to take part in a clinical research study. Before you decide it is important for you to understand why the research is being done and what it will involve for you. Please take time to read the information sheet carefully and discuss it with others if you wish. Please ask us if there is anything you are unclear about or if you would like more information. Take time to decide whether or not you wish to take part.

What is a 7T MRI scanner?

Since the 1970s, magnetic resonance imaging (MRI) has been shown to be a safe diagnostic imaging procedure. The magnetic field strength of an MRI scanner is measured in Tesla (T). 1.5T scanners are now standard diagnostic tools used within the clinical service, with 3T systems introduced for more specialist clinical imaging. Across the world there are about 50 centres using ultra-high field (7T-11.7T) scanners for human imaging. Currently such use is for scientific and clinical research only.

Is a 7T MRI scanner safe?

The 7T scanner at Queen Elizabeth University Hospital is not currently CE Marked, which means that it can only be used in a research setting with appropriate Ethics approval. The purpose of CE Marking is to show that the equipment complies with the relevant European health, safety and environmental protection legislation. The scanner has been built and tested in accordance with this legislation. In addition, recent Health Protection Agency and European (ICNIRP) advice has stated that field strengths up to 8T can be safely used as long as the participant is aware of the possibility of dizziness when moving into and out of the MRI scanner.

What is the purpose of this study?

Our research team has considerable experience of conducting research studies using 1.5 and 3T MRI imaging. However, the 7T MRI unit at the Imaging Centre of Excellence (ICE) on the Queen Elizabeth University Hospital campus is new and before we start conducting research using this scanner it is important that we can conduct quality assurance studies to optimise the images that we generate.

At this point our aim is to establish good image quality with protocols that have previously been tested and run in human participants in other 7T centres. We will only be scanning brains for this study, and will not be testing new or “untried” techniques.

You may be invited back for repeat scans to ensure that we are able to reproduce the imaging protocols consistently or if there were any technical issues during your first scan.

Why have I been invited to take part?

All healthy volunteers in this study will be selected to have had a prior brain MRI scan as part of an ethically approved protocol. You have been approached by a member of the research team because of your previous scan, and you have no known health problems. Your involvement will allow us to make sure that the quality of MRI scans is as good as possible before the actual study begins.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form, and given a copy to take home. If you decide to take part you are still free to withdraw at any time and without giving a reason.

What will happen to me if I take part?

When you come for your scan, we will discuss the study with you and if you want to take part you will be asked to sign a consent form. A member of the research team will also take you through a pre-scan checklist to make sure that it is safe for you to enter the scanner. Once you have been approved to enter the scanner you will be asked to change into a gown and taken into the MRI room.

Once in the MRI room, you will be positioned on the table. Equipment shall be placed over your head that fits like a loose helmet. This equipment is called a 'coil' and the information that it receives is what produces the images of your brain. It does not hurt in any way. The table will then move into the scanner, and the scan will begin.

You will be given earplugs or headphones to reduce the noise generated by the machine to an acceptable level. Some participants may potentially find the process of an MRI scan claustrophobic. You will be monitored throughout the scan and will be able to communicate with the research team via an intercom should you wish to stop at any time.

In some cases we may ask you to attend for further scanning and repeat the MRI scan to check if the new technique gives the same results each time.

If the repeat scan is to be done on the same day we will bring you out of the scanner for a break and refreshment. Any effects that you experience from being in the scanner e.g. dizziness will pass once you are removed from the scanner. When you are ready we will repeat the scan. It is likely that you will feel the same effects when you go back in for repeat scanning. The total time for this will not exceed 2 hours of scanning time. Or we may ask that we book the repeat scan for another day which suits you.

You do not have to attend for any repeat scanning if you do not wish and may change your mind at any time, even after a first or second scan, and pull out of the study.

The specific details of the scan which we would like you to have are provided at the end of this document.

Do I need to do anything before the scan?

There is no preparation required on your part before having the scan.

What are the risks involved in participating?

If you have any implants or devices in or on your body or any tattoos then you will not be allowed to take part in this study. This is because the scanner is a powerful magnet and uses radio-waves, and implants could move or heat up. Similarly, there is a risk that the pigment used in tattoos could heat up during scanning. You will be taken through a safety checklist prior to entering the scanner room to determine if it is safe for you to participate. A copy of the checklist is attached at the end of this document, and we would ask you to read through it and contact Dr John Foster on 452 4218 before your scan if you answer “yes” to any of the questions, or if you have any concerns. It is very important that you answer the safety checklist honestly and that you seek clarification for anything which you do not understand. The safety checklist will be treated confidentially.

If you have had surgery of any kind or are unsure of any of the answers, it is not a problem, but we will err on the side of caution and will not scan you.

It is possible that you may feel dizzy when moving around in the scanner room. This is completely normal, and the feeling will pass when you lie down on the scanner bed or leave the scanner room. There are no known long-term effects from exposure to the magnetic field used in 7T MRI.

After your scan, you will be monitored to ensure that any dizziness has passed. Study participants should not drive for 15 minutes after being scanned. A refreshment will be offered while you wait.

What are the benefits in my participation?

You will not receive any direct benefit from the scan, but the information that we get may improve the quality and amount of information that can be obtained from scans in subsequent clinical trials, and hence help to improve treatment of patients in the future.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. All images collected from the scans will be anonymised before any analysis is carried out on them, therefore you will not be able to be identified from the images in any way. Your personal information will be kept on file and stored in a secure place at the Imaging Centre of Excellence, Queen Elizabeth University Hospital.

However because we are working in partnership with the scanner manufacturer (Siemens) to develop 7T imaging protocols your imaging data will be visible to them on the scanner i.e. your name and date of birth. However if we choose to share any scans with them for analytical or marketing purposes, such scans will always be anonymised.

How will the images from my scan be used?

Your images will help us to decide what we need to do to make sure that the scans we use in future research studies are as good as possible. We may also use your images to test analysis software. Your images may be used in scientific presentations and for teaching purposes, but no information will be used that would allow you to be identified. Your images may be shared with the manufacturer (as above).

Will my GP be informed?

We do not intend to routinely contact your GP; however, you may choose to discuss your involvement with your GP yourself. Because 7T MRI is not in clinical use, your images will **not** be reviewed by a doctor. In the unlikely event that an abnormal finding is detected, then we will contact you and will make arrangements for you to have a 3T scan. You will then be referred to an appropriate specialist for further investigations. You should be aware that you may then have to disclose such findings in future applications for health-related insurance.

What will happen to the results?

You will not be informed of the results of your scan. The results of the analysis will be used to improve our techniques for use in larger clinical studies initially, and hopefully to provide an improved service to patients in the future.

What if there is a problem?

This study is sponsored by NHS Greater Glasgow & Clyde. The sponsor will be liable for negligent harm caused by the design of the trial. NHS indemnity is provided under the Clinical Negligence and Other Risks Indemnity Scheme (CNORIS). If you have any complaint about the way you have been dealt with during the study you should discuss this with the research team in the first instance. In the unlikely event that something does go wrong and you are harmed during the research study there are no additional compensation arrangements. The normal National Health Service complaints mechanism is also available to you and the contact telephone number for this is 0141 201 4500.

Who has reviewed the study?

The study has been reviewed and approved by the West of Scotland Research Ethics Committee 3 and NHS Greater Glasgow & Clyde Research and Development Department.

Thank you for taking the time to read this information sheet. If you have any questions or would like some more information, please feel free to contact a member of the research team and discuss it with them.

**For further information on the study,
please contact:**

Dr John Foster
Consultant Clinical Scientist (MRI)
Queen Elizabeth University Hospital
Tel: 0141 452 4218
Email: johnfoster2@nhs.net

**For independent advice on participating in research,
please contact:**

Dr Ruth Hamilton
Consultant Clinical Scientist
(Paediatric Physiological Measurement)
Royal Hospital for Children
Tel: 0141 452 4217
Email: ruth.hamilton@glasgow.ac.uk

IMAGE OPTIMISATION FOR 7T MRI RESEARCH STUDIES

Details of 7T MRI Scan

Area of Body Brain *Specify here if fMRI etc.*

Expected Total Time for Visit

Expected Time in Scanner

Further Information

The text in this section will be reviewed by the CRIF Approval Group for each optimisation project.

When you come for your scan, you will lie on you back on the scanner bed. We will place a coil over your head to allow us to take images of your brain, and will then move you head-first into the scanner.

During some of the scans we may ask you to perform a series of tasks. These tasks may involve looking at visual information, listening to sounds through a set of headphones or responding to external stimulus such as heat applied to your hand or arm. You will be shown examples of any tasks in order to make sure you are comfortable with them before beginning the scan.

It is important that you stay completely still during your scan (unless we instruct you to move as part of a task) since any movement will cause blurring in the images. The radiographer will be in contact with you via intercom throughout the scan, and you will be given a buzzer to press if you wish to stop the scan at any time.

	Clinical Research MRI Facility Screening Form MR Controlled Access Area including Scanner Room	
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Assessed for 3T <small>Please vet</small>		Name: _____ Address: _____ Date of Birth: _____ CHI: _____ Phone number: _____
Assessed for 7T <small>Please vet</small>		

Study name:	R&D number:	Investigator:
Study ID:	Weight:	Height:

Have you ever: Had a cardiac pacemaker, implanted defibrillator or pacing wires?	YES	NO
Had any surgery/procedure to your heart? ■ If yes, give details.....	YES	NO
Had any surgery on your neck, head, brain or eyes? ■ If yes, give details.....	YES	NO
Had any surgery involving the use of metal implants, plates, or clips? ■ If yes, give details.....	YES	NO
Had any implanted, attached or ingested electronic, mechanical or magnetic devices? ■ If yes, give details.....	YES	NO
Had any other surgery? ■ If yes, give details.....	YES	NO
Had metallic injuries or metal fragments in your eyes /other parts of the body?	YES	NO
Have metal dentures/dental plate, hearing aid or wig?	YES	NO
Wear a fake limb, cast or brace?	YES	NO
Have any tattoos, permanent makeup or body piercing?	YES	NO
Wear any type of skin patch? ■ If yes, give details.....	YES	NO
Contrast examinations – 3T only: Have any kidney problems, kidney failure or ever had dialysis?		
Have asthma, eczema, hayfever, or any known allergies? ■ I will accept a contrast agent injection if required.	YES	NO
Females: Could you be pregnant? ■ LMP date:		
■ Have you been sterilised or have an IUD fitted?	YES	NO
■ Contrast examination: Are you breast feeding?	YES	NO

Before entry into the examination room all metallic objects must be removed: Metal tools, scissors, keys, watches, papers, credit cards, coins, hair clips, hearing aid, jewellery and all other metallic items upon my person.

I have read and understood the contents of this form and confirm that the answers to the above safety questions are correct to the best of my knowledge. I have had the opportunity to ask questions about the MRI procedure that I am about to undergo.
 Staff/participant/patient/visitor:

Name: _____ Signature: _____ Date: _____

Authorized Scanning Staff Member:

Name: _____ Signature: _____ Date: _____