The ROYAL MARSDEN
NHS Foundation Trust

The MALIMAR Study Healthy Volunteer Consent Form

Studv Reference Numbers: CCR 4820: IRAS No.: 233501

NHS No. ☐☐☐☐☐☐☐☐☐☐

Healthy volunteer Trial ID: ☐☐☐☐☐☐☐☐☐

Name of Lead Researcher: ……

Please initial box

1. I confirm that I have read and understand the Healthy Volunteer Information Sheet version 2.0 dated 07/12/18 for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. If I request withdrawal from the study, I give permission that my data already collected within the study can be anonymised and used. ☐
4. I understand that relevant sections of my medical notes may be looked at by responsible individuals from the research team, from regulatory authorities or from the NHS trust where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
5. I consent to undergo an MRI scan under the supervision of the responsible clinician for this research. I understand that if any health related issues come to light as a result of undergoing this scan, otherwise known as 'incidental findings', that I and my General Practitioner will be promptly informed of these issues. ☐
6. I agree to participate in the MALIMAR study. ☐
7. I give permission for the data collected during the study to be used in further ethically approved research within and outside the UK in the field of imaging research. I understand this will not include any personal data from which I could be identified. ☐

Name of Healthy Volunteer	Date	Signature
Name of person taking consent (PI or approved signatory)	Date	Signature

Original for Investigator's Site File; 1 copy for volunteer; 1 copy for hospital notes; 1 copy to be sent to RM-CTU

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MALIMAR

Healthy Volunteer Information Sheet

Development of machine learning support for reading whole body diffusion weighted magnetic resonance imaging (WB-DW-MRI) in myeloma for the detection and quantification of the extent of disease before and after treatment.

Short Title: MAchine **L**earning **I**n **M**yelomA **R**esponse

7th December 2017

Version 2.0

CCR Number: 4820

IRAS (Integrated Research Application System) No. 233501

You are being invited to take part in a research study. Before you decide whether or not to take part it is important for you to understand why we are doing this research and what it involves. Please take time to read the following information carefully and discuss it with relatives, friends, and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time deciding whether or not you wish to take part.

You can learn more about clinical research on the Cancer Research UK's patient website (www.cancerhelp.org.uk)

Invitation

If you are 40 years or above the Radiology Department at the Royal Marsden hospital would like to invite you to take part in a research study. This will involve you having a particular type of Magnetic Resonance Imaging (MRI) scan known as a Whole-Body Diffusion Weighted MRI scan or 'WB-DW-MRI'.

Before you decide to participate it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Thank you for reading this Information Sheet.

What is the purpose of the study?

There have been enormous advances in recent years in the technology used to take pictures (images) of the internal anatomy of cancer patients to better identify sites of disease. These images (or scans) can now provide a more accurate indication of the scope or spread of disease. They can also be used for assessing disease response to different drugs or treatments.

MRI (magnetic resonance imaging) has the advantage over other types of scanning (e.g. computerised tomography or 'CT') in that it does not involve the delivery of any radiation dose. In particular, a new type of MRI, called Whole Body Diffusion Weighted MRI (WB-DW-MRI) can provide especially precise images of diseased compared to healthy tissues. As a result, it is now being more widely used in cancer treatment centers throughout the world.

Despite these advantages, WB-DW-MRI has an important disadvantage. Each scan is made up from over a thousand images, each of which needs to be read and interpreted by an expert Radiologist. Thus, the time taken to read a single WB-DW-MRI scan is much longer than for a normal MRI scan, meaning that few NHS treatment centres (or hospitals) are able to offer them to patients.

Members of the research team from the Royal Marsden Hospital and Imperial College London have already undertaken some work to ascertain how computers can reduce the time taken to read WB-DW-MRI scans. The technique is called 'machine learning' and basically teaches a computer to detect areas of suspicion or concern for disease on WB-DW-MRI scans. The 'trained' computer can then make an initial and very rapid interpretation of the images taken during a scan. These images can then be presented to the expert radiologist to make the final interpretation. In addition to training computers to read scans more quickly, we also want to train computers to interpret differences between scans taken from the same patient at different time-points. This will allow us to accurately assess change in disease extent or response to treatment over time.

However, in order to train the computers, we need examples of WB-DW-MRI images taken from both diseased (cancerous) and healthy tissues. In this study we are concentrating on patients with myeloma (cancer of white blood cells). We have already acquired WB-DW-MRI images from many patients with this type of cancer. **So now, we are seeking your help to acquire WB-DW-MRI images from healthy tissues for the M**achine **L**earning **I**n **M**yelom**A R**esponse (**MALIMAR**) study**.**

<u>What will happen to me if I decide that I would like to take part?</u>

Before we can enter you to the study, we will need to check that you can have an MRI scan and that you are suitable to take part. Some people cannot have an MRI scan. These include people with a pacemaker, metal heart valves, aneurysm clips in the brain or people who have had metal fragments in their eyes. In addition, we are unable to include volunteers who have had or have a significant illness as this may affect the scan.

It may also not be appropriate for you to take part if you have had extensive surgery previously. Our study researcher will confirm these points with you before you are admitted to the trial. As advised above we are only recruiting volunteers aged 40 and above: anyone under this age will have to be

excluded from participating because they will not be a suitable comparator. Once we have confirmed that you are suitable to enter the trial, we will ask you to sign an Informed Consent Form and then book your scan. Some volunteers may be asked to attend early evening or week-end appointments to avoid busy times during the day when the MRI Unit is reserved for patients. There are usually no special preparations and no injection or drugs will be given. All instructions for the scan will be in your MRI appointment letter. When you come for the scan you are advised to wear clothing without metal fastenings and to avoid using make-up or mascara. You can wear glasses, but will need to take these off during the scan. A locker will be provided for your valuables.

The MRI scan will be carried out by radiographers who are trained to carry out the scans. MRI uses a magnetic field and radio waves to build up detailed images of your internal anatomy by detecting signals sent out by water molecules. It is not painful, but you will have to lie still for the duration of the scan which can be up to 60 minutes. The scanner produces a variety of loud noises during the scan which are made by the magnetic coils that switch on and off during the scan. These are important in measuring the signals from your body to create the images. They are switched on and off very quickly and they vibrate, which is what causes the noise.

Some people may find the noise level uncomfortable and the table quite hard to lie on. You will be provided with earplugs to help reduce the noise. The scanner is open at both ends, but some people may find it claustrophobic. During the scan the radiographer can see you from the control room and can talk to you through an intercom. You will be given a call button to press to alert attention and can listen to music during the scan. You can leave as soon as your scan is finished and can eat and drink as normal. There are no side effects from the MRI scan itself.

Why am I being invited to take part?

You will be reading this Information Sheet because you have responded to one of our advertisements for Healthy Volunteers to take part. If we invite you to sign a Consent Form then you are eligible to take part in the study. If you are not eligible to participate we will explain the reason.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do choose to take part you will be asked to sign a consent form, a copy of which will be given to you for your records along with this information sheet about the study. Your legal rights are not affected by participation in the study.

What happens if I change my mind during the study?

Your participation in this study is entirely voluntary. If you agree to take part and then change your mind and wish to withdraw, you may do so at any time. If you decide to not join the study or to discontinue in the study, this will not affect any future care or treatment you receive.

What are the risks and the benefits of taking part in this study?

A possible risk in taking part is a degree of discomfort you may encounter in undergoing the MRI scan. As we said above, unlike other forms of imaging (e.g. CT scans) MRI does not deliver radiation and no drugs or other medication will be given. You will be registered on the Royal Marsden Hospital Information System and a report of your scan results will be held on this system. If an unexpected finding of concern is discovered, a doctor will call you to discuss your scan report. We will also send a copy of the report to your GP who will then advise you regarding any follow-up investigations that may be needed. This could lead to some anxiety. If unexpected findings are discovered which are not concerning, we will send you a letter to explain the findings and copy this letter to your GP. You may then wish to call us or your GP for more information. If there are no unexpected findings we will not contact you or your GP.

In general, the research will not be of direct benefit to you, but may prove to be of benefit to others in the future. However, possible benefits are that you may find it satisfying to have contributed to medical research and, should an unexpected finding be discovered you may feel that the early detection and diagnosis will result in a better outcome. If you wish to have a copy of your scan report, you may ask for this.

What if something goes wrong?

It is unlikely that anything will go wrong but, if you wish to complain, you can do so using the normal NHS complaints procedure. If taking part harms you in any way, there are no special compensation arrangements, but the hospital would be liable for any negligence on the part of hospital staff. Your legal rights are not affected by giving your consent to participate in this study.

Who is organizing and funding the research?

This study is being organised by The Royal Marsden NHS Foundation Trust with participation from The Institute of Cancer Research, Imperial College London and Imperial Healthcare NHS Foundation Trust. The study is being funded by a National Institute for Health Research grant as part of their Efficacy and Mechanism Evaluation programme.

Will my taking part in this study be kept confidential?

1) Clinical Information: You will need to be given a Royal Marsden hospital number in order to receive the WB-DW-MRI scan. The resulting scan report will be held on our clinical Hospital Information (NHS PACS) System which is the system we use for holding all NHS patient information. Access to this system is subject to the normal Trust-based information governance controls. If, in the event of unexpected findings, you require further diagnostic investigations, your GP will be informed and your scans and accompanying data will be made available to the hospital treating you.

2) Research Information: Your scan data will be anonymised and identified by a unique trial identification number. Your unique trial number will be used to make sure you cannot be identified by members of the research team that are not part of the NHS staff at RMH. The data from your scan which will be used in the MALIMAR study will only be available to authorised members of our research team so they can collect information needed for this research study and also to check that it is correct. All information will be kept confidential, and your name, date of birth and other identifiable information will be removed from your scans prior to archiving. We will also ask you to consent to allow your data that has been collected in the study to be sent outside of the UK and to be used in future ethically approved studies. This information will not include any personal information that could directly identify you.

What will happen to the results of this study?

As soon as there are reliable results, they will be published in a respected peer reviewed medical journal and presented in various scientific meetings. Your identity will not be revealed in any report, publication or presentation. The results will be available on request.

How is the trial monitored for safety?

This study has been carefully planned by leading cancer specialists and approved by the Oxford C Research Ethics Committee (REC), the Royal Marsden Hospital Committee for Clinical Research (CCR) and the Health Research Authority (HRA). The members of the study team will be meeting at regular intervals to monitor the progress and safety of the study. Full (100%) monitoring will be carried out to ensure that where incidental findings come to light, both you and your GP are promptly informed.

What do I do now?

We would be happy to answer any questions you may have about the study. You can telephone us, or speak to us again. Please discuss this information with your family, friends or your GP if you wish. If you require further information about this study please contact:

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Thank you for reading and considering taking part in this study.

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