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# Participant Information Sheet

## Advanced Imaging with Safe Tracers to Study Multiple Sclerosis MISSION-MIMS – Deuterium substudy Healthy Volunteer

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## Introduction

We're inviting you to join a research study, and it's important that you understand why and what it will mean for you. Please take your time to read this document, discuss it with others, and feel free to ask us any questions. Signing the consent form is your choice and you can change your mind at any time.



The study is organized by the Department of Radiology, University of Cambridge and Cambridge University Hospitals NHS Foundation Trust. The study is funded by the [NIHR Cambridge Biomedical Research Centre](#) and [MS Society](#).

## What is the purpose of this study?

**Multiple sclerosis (MS)** is a condition that affects the brain and is linked to changes in the body's immune system. MRI scans are an important part of diagnosing and monitoring MS because they allow doctors to see changes in the brain over time.

An MRI scanner is a large, tube-shaped machine (**page 17**) that uses strong magnets and radio waves to create detailed pictures of the brain. During the scan, a lightweight plastic frame, called a coil (**page 17**), is placed around your head to help produce clear images.

In this study, we are using a newer MRI technique to learn more about how MS affects the brain. This scan is called **Deuterium Metabolic Imaging (Deuterium MRI)**. It works similarly to a standard MRI scan but allows us to see chemical changes in the brain that are not visible with routine imaging.

Deuterium MRI involves **drinking a solution** that contains either sugar (glucose) or water, both of which have been labelled with deuterium. **Deuterium** is a safe, non-radioactive form of hydrogen that is already naturally present in your body (**page 9**). Using MRI, we can detect deuterium and learn more about how your brain uses glucose.

To better understand what is “normal,” we need the help of **healthy volunteers**. Their scans provide a baseline of how a typical brain looks on these MRI techniques, which helps researchers compare and interpret changes seen in people with MS.

## Why have I been invited?

For this study, we will invite two groups of people to take part:

- People who have been diagnosed with multiple sclerosis.
- Healthy volunteers who have not had any brain condition.

You have been invited to join this study because you are healthy, and we expect you to have a normal MRI scan.

## Do I have to take part?

You do not have to agree to take part. We will discuss the study with you and answer all your questions. We will ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason.

## Criteria that may exclude you from participating

You might not be eligible if...

...you have a heart pacemaker, cardiac stent, cochlear implant or certain metal devices or any other significant medical or psychiatric history.

...you're pregnant, nursing, or planning for a baby, please inform us.

...you're a woman of childbearing age, we'll ask you to use contraception two weeks before and after each imaging visit and agree to a pregnancy test before scanning.

...you're a man, we'll ask you to use contraception for two weeks post-imaging. We'll discuss about suitable options before you give your consent.

**Your wellbeing is our priority!**



## What will happen if I take part?

If you choose to help us, we will carry out certain study procedures. We anticipate your visit will take up to **2 hours**.

### Consent Process (30 min):

- If you decide to participate after reading this information sheet and having an opportunity to talk to us, you'll be asked to provide your written informed consent.
- We may ask you to fast (avoid food and drink) for up to six hours before your scan. However, if you are unable to do so, it is okay to have small snacks. Fasting is not essential, and you can still take part in the study.
- Some research activities are optional, opting out of these won't affect your participation in others.

### Appointment Booking:

- Your research MRI scans will take place at either the **MRIS Unit** or the **Wolfson Brain Imaging Centre**, both at Addenbrooke's Hospital (**page 18**).
- We will do our best to find the most suitable day and time.

### Safety Checklist (10 min):

- Please remove metal items before the scan.
- Before the MRI scan, a qualified team member will go through a metal safety checklist with you.
- We will ask about your medical history and basic details such as age, height, weight, and gender.
- We may carry out some routine health checks, for example a brief medical examination, a blood sample, a pregnancy test (for women who could become pregnant).

## What will happen if I take part?

### Before the MRI Scan (10 min):

- You will be asked to drink 200 ml of a special solution containing deuterated glucose or deuterated water before the scan. This will be done outside the scanner, and you may need to wait up to 90 minutes before the scan starts.
- A small blood sample may be taken (about 3 tablespoons).

### During the MRI Scan (60 min):

- After the healthy checks and received your signed consent, you'll be guided to the MRI scanner. You'll lie on a movable bed that slides into the MRI scanner. We will place your head inside a coil which is used to send and receive radio-frequency waves that interact with the body's tissues.
- The radiographer will operate the scanner from the control room, with constant observation and a two-way intercom.
- While inside the scanner, you will have Deuterium MRI.
- Expect to lie still for about **60 minutes**. Feel free to ask for a break.

### After the MRI Scan (10 min):

- Another blood sample may be taken (about 3 tablespoons).



## What will happen if I take part?

### Optional Repeat Scan:

- You may be invited to return for a second, **optional** scan within **14 days**.
- This might involve the same scans again, or a different type of scan, where you receive an injection of another sugar called pyruvate instead of drinking a glucose solution. You would receive a separate information sheet explaining this in detail.
- Taking part in this extra scan is completely **optional** and will not affect your care.
- We will offer you the choice to be on a research database for future study invitations; it is **optional**.

This process aims to ensure your comfort, safety, and active participation. Feel free to ask questions or share concerns at any point.

## What are the possible benefits of taking part?

Taking part in this study will not directly benefit you, but the information gained may help improve care for people with multiple sclerosis in the future.

## Reimbursements

You will not be paid for taking part in this study. However, we will reimburse reasonable travel and parking costs related to your participation.



## What are the possible risks/side effects of taking part?

### MRI:

MRI scans are safe and don't involve X-rays or radioactivity. Some of the equipment used is meant for research, not routine diagnosis. Some people may feel 'closed in' (**claustrophobic**). You'll have a 'squeeze-ball' alarm, and we can stop the scan at any point if you ask us. MRI machines make **loud noises** such as banging, clicking, whirring, clanging, and beeping. This is normal. We will provide headphones and earplugs. You're always visible and you can communicate with the staff during the scan.

### MR Coils:

In this study, we will use specialised MRI equipment, such as coils that may not have a CE mark, which means they are not formally approved for routine clinical use. The MR coils and associated software are being put together in-house and therefore there is no external regulatory checks on the safety or performance of these devices prior to their use. These coils and related software are commonly used in research settings around the world for imaging. While rare, faulty coils could cause a local increase in body temperature or, in extreme cases, a **minor skin burn**. To minimise this risk, all equipment will be carefully tested before use and standard hospital safety procedures will be followed.

### Deuterated Glucose or Water Drink:

Glucose and water drinks are safe; deuterium isn't radioactive. While **allergic reactions** are rare, we're prepared to manage them.



### Fasting:

Fasting before the scan may make you feel **hungry, thirsty, tired, or light-headed**. Some people may also **feel irritable** or have **trouble concentrating**, and those with certain medical conditions may experience **low blood sugar**. Rarely, fasting can cause **dizziness or fainting**. If you feel unwell at any time, please eat or drink as needed. Let the study team know if you have any medical conditions that could make fasting risky.

### Other studies:

Taking part in this study while participating in other studies might be difficult for you and research teams. If you're already in another study or are thinking about joining one, please let us know.

### Incidental Findings:

Your scans **are not** for diagnosis but may reveal a significant abnormality. If we find something important, with your consent, we'll discuss it with you and your GP. It may identify something you weren't aware of. If you cannot consent to being informed of an unexpected finding, you will be ineligible to take part in this study. Your healthcare remain unaffected.

## **Is there any compensation if something goes wrong?**

If anything goes wrong because of a mistake on our part, Cambridge University Hospitals NHS Foundation Trust will take full financial responsibility.

The University of Cambridge has insurance to cover any harm related to how the study is set up or any unintentional problems during your participation.

## **What will happen if I don't want to continue with the study?**

Feel free to step back from the study anytime – no need to explain why. Just let us know through phone, letter, or email. It will not affect your future healthcare. Your ability to access, change, or move your information is limited because we need to handle it in specific ways to ensure the research is accurate and reliable. After withdrawal, we will still keep the information we have already collected about you but will use only the minimum personal details.

## **Who has reviewed the study?**

All NHS research, including our study, is assessed by an independent committee to ensure your safety, rights, and wellbeing. Our study has been reviewed and earned a positive opinion from the Research Ethics Committee.



## Who will have access to the scans and results?

We will store data securely and the security will be overseen by Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge (**page 13**). Only the study team will have access to the non-anonymous scans and data.

We may share **pseudonymised**<sup>1</sup> data with others working in a similar field, and this may include research organisations and companies working abroad (**page 14**).

## Will my taking part in the study be kept confidential?

Yes, we'll keep your details confidential. We won't share that you're part of the study with anyone without your consent.

## Will my GP be informed?

It is your choice, but we recommend that your GP is kept informed particularly of any unexpected observations.



<sup>1</sup>Pseudonymization is a process where personal information in a data record is replaced with unique codes, making the data less identifiable but still possible to link back to the original person if needed.

## **What happens at the end of the study?**

We will analyse the information we collect from the images. We will use the results of this study to help develop new imaging methods that improve how multiple sclerosis is identified and understood in the brain.

We plan to share our study findings by publishing in medical journals and presenting at scientific meetings, both nationally and internationally. This research might be included in a PhD thesis for a student on our research team. All personal information collected during the study will be kept confidential at all times.

We're happy to send you a written summary of the study results, though we can't provide individual results directly. If you're interested, let the researcher who got your consent know, and share your email address on the consent form.

## **What will happen to my samples?**

Any samples taken from you, such as blood samples, will be labelled with a study code rather than your name. This code allows the research team to link your samples together, but it does not identify you personally. Only the main research team will be able to connect this code to you.

Your blood samples will be tested to measure certain substances in the blood. These results will be compared before and after the deuterium drink to see if there are any changes. This helps us better understand how the body responds during the scan.

Once all the planned tests have been completed, your blood samples will be safely disposed of.

## How will we use information about you?

We will need to use information from you, and your medical records for this research project.

This information will include your initials, NHS number, name, contact details and date of birth. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

Cambridge University Hospitals NHS Foundation Trust and The University of Cambridge is the sponsors of this research, and is responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- NHS trusts and healthcare providers involved in your care
- Research collaborators (anonymised data only)
- Auditors/inspectors appointed by regulatory bodies, if requested
- Academic publishers (anonymised data only)

We will keep all information about you safe and secure by:

- We will keep all information about you safe using secured files or transfers and treating it in the strictest confidence.
- Data and images from the MRI examinations will be stored securely on encrypted servers during the course of the study.
- Only authorised researchers involved in the study will have access to view data that can identify you. Study researchers analysing the images will not be able to identify you, as these images will have no personal information attached.

## International transfers

We may share or provide access to data about you outside the UK for research related purposes to:

- Access the necessary skills or facilities to analyse specific data may be located outside the UK
- Involve global teams to improve research quality and findings.
- Be used in future ethically approved studies.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be our collaborators who analyse your data.

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website:   
<https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/>

- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website:   
<https://ico.org.uk/for-organisations/report-a-breach>.

## **How will we use information about you after the study ends?**

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 10 years. The study data will then be fully anonymised and securely archived or destroyed.

## **What are your choices about how your information is used?**

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

## **Where can you find out more about how your information is used?**

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK.

- our leaflet [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)
- by asking one of the research team
- by sending an email to [cuh.gdpr@nhs.net](mailto:cuh.gdpr@nhs.net), or
- by ringing us on 01223 256989.

## Contact details for further information

If you have any further questions, you can contact the study team during office hours (**9am to 5pm**). If you're unwell, feel different, end up in the hospital, or visit the emergency department, please let the study team know. If you have any concerns about how you have been treated or any potential issues, please contact the study team. You can also make a formal complaint through the NHS Complaints Procedure.

Telephone: **01223 767926 or 01223 256989**

Email: [cuh.radiologyresearch@nhs.net](mailto:cuh.radiologyresearch@nhs.net)

### Out of Hours

If you join the study and need help after hours, call your GP's number. If they're closed, you will get redirected or receive guidance via a recorded message.

### At any time

Failing to contact one of the above numbers at any time, please contact

A&E department: **01223 217118**

### For complaints

Patient Advice and Liaison Service (PALS)

Telephone: **01223 216756**

Email: [cuh.pals@nhs.net](mailto:cuh.pals@nhs.net)



## Additional information

If you are invited for an optional repeat scan, it doesn't mean we found anything unusual. These scans are only for technical reasons.



Our MRI scanner



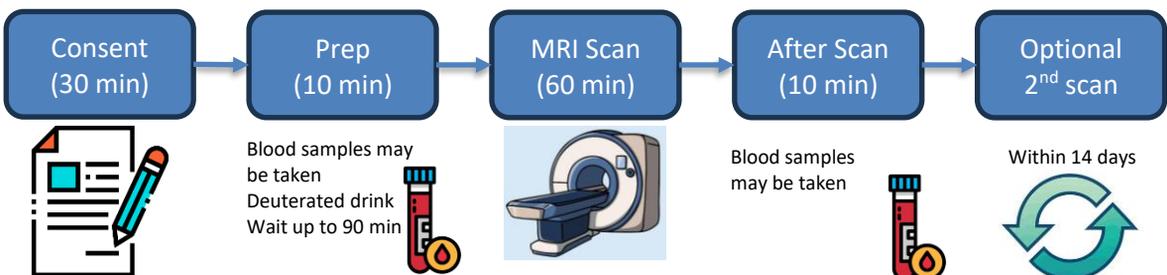
The coil for MRI imaging.

## What to expect during MRI scan:

<https://www.youtube.com/watch?v=g-jj4KrmYPI&themeRefresh=1>



## Study flowchart



***Thank you for your interest in the study. If you need more information, just reach out – we are here to assist you.***

A copy of the consent form will be provided for you.

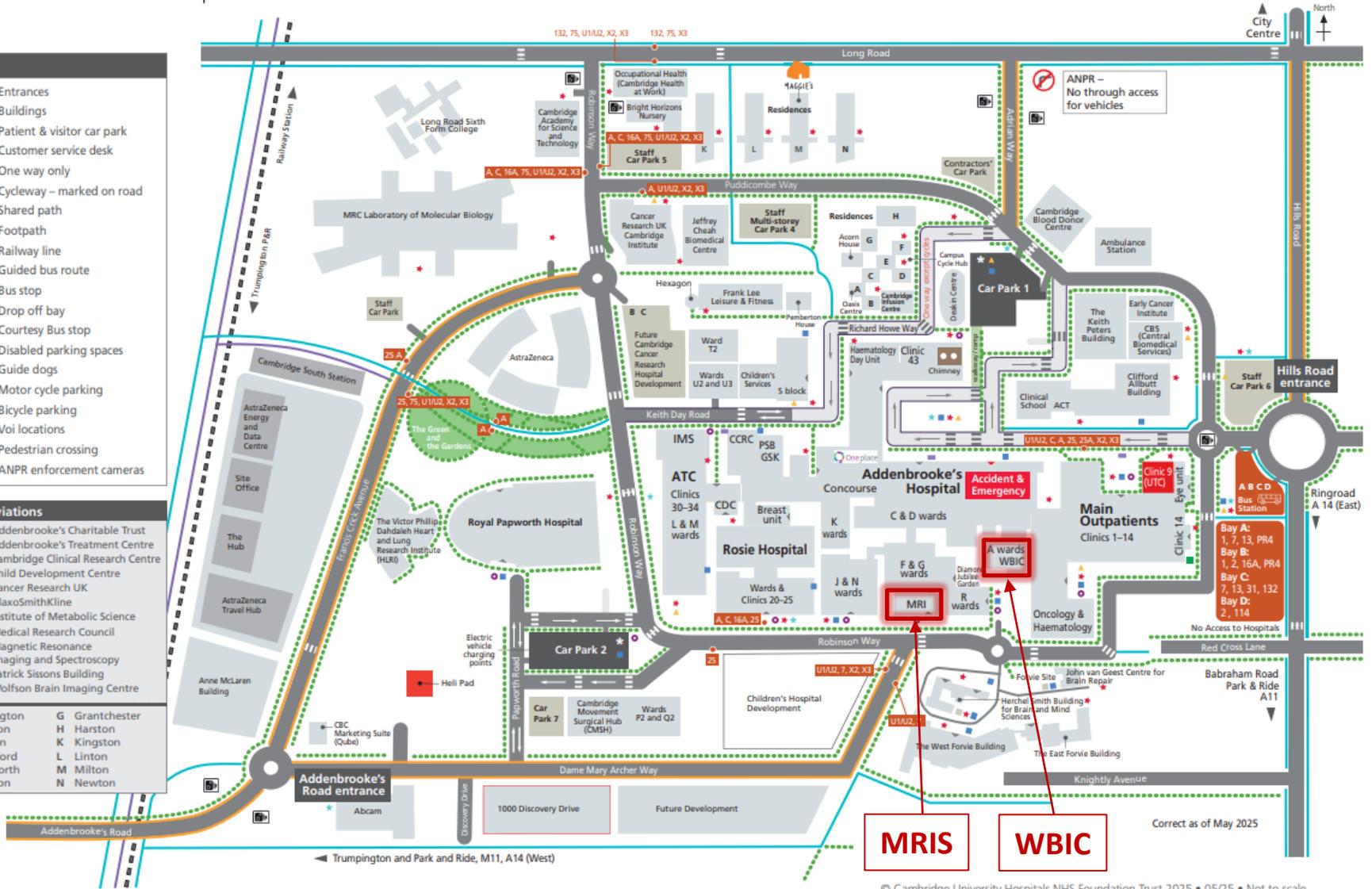
### Key

- Entrances
- Buildings
- Patient & visitor car park
- Customer service desk
- One way only
- Cycleway – marked on road
- Shared path
- Footpath
- Railway line
- Guided bus route
- Bus stop
- Drop off bay
- Courtesy Bus stop
- Disabled parking spaces
- Guide dogs
- Motor cycle parking
- Bicycle parking
- Voi locations
- Pedestrian crossing
- ANPR enforcement cameras

### Abbreviations

ACT	Addenbrooke's Charitable Trust	G	Grantchester
ATC	Addenbrooke's Treatment Centre	H	Harston
CCRC	Cambridge Clinical Research Centre	K	Kingston
CDC	Child Development Centre	L	Linton
CRUK	Cancer Research UK	M	Milton
GSK	GlaxoSmithKline	N	Newton
IMS	Institute of Metabolic Science		
MRC	Medical Research Council		
MRIS	Magnetic Resonance Imaging and Spectroscopy		
PSB	Patrick Sissons Building		
WBIC	Wolfson Brain Imaging Centre		

A	Abington	G	Grantchester
B	Barton	H	Harston
C	Coton	K	Kingston
D	Duxford	L	Linton
E	Elsworth	M	Milton
F	Foxton	N	Newton



**MRIS**      **WBIC**