Participant Information Sheet

Exploring new MRI techniques - a study in healthy volunteers and healthy patients (HeVoMRI)

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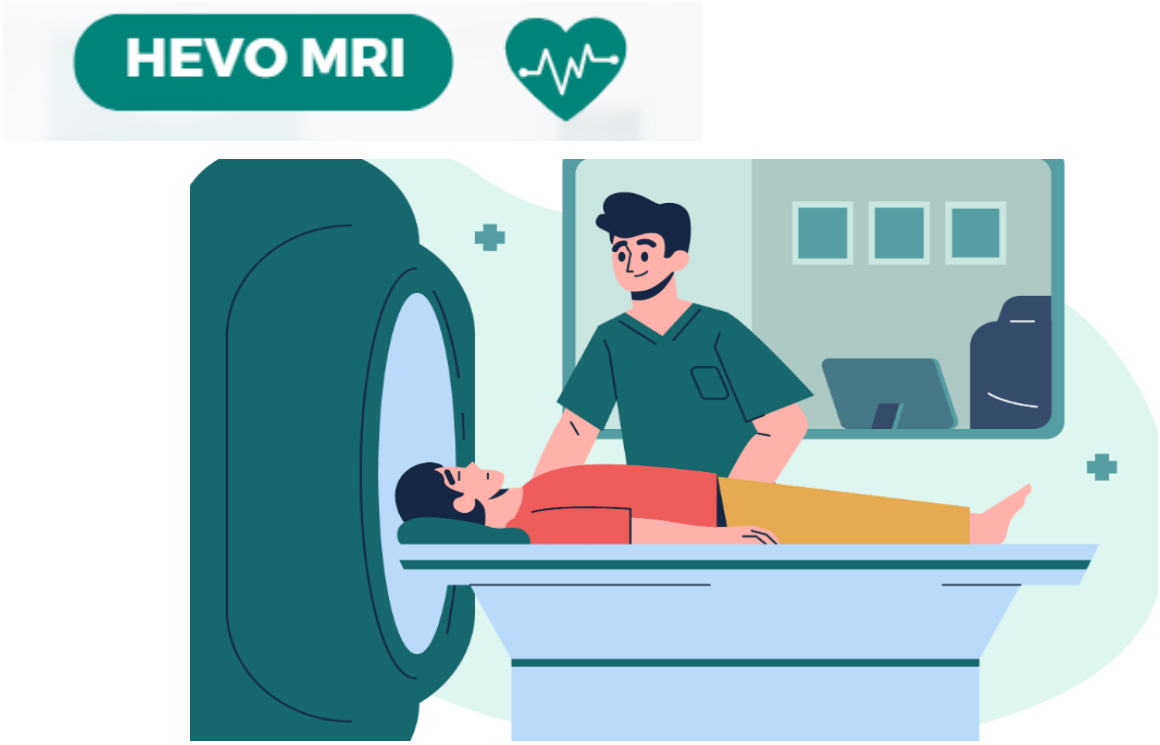
Introduction

We're inviting you to join a research study, and it's important to understand why and what it will mean for you. Please take your time, 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.



This study is conducted by the Department of Radiology at the University of Cambridge and Cambridge University Hospitals NHS Foundation Trust, with funding from the Cancer Research UK, which focuses on cancer research.

NIHR | Cambridge Biomedical Research Centre

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CANCER RESEARCH UK

What is the purpose of this study?

Magnetic Resonance Imaging (or MRI) plays an important role in detecting, diagnosing, and monitoring different diseases in the body. We often use contrast-enhanced MRI, which enhances and improves the quality of the MRI images. This type of MRI involves an injection of a chemical substance called gadolinium-based contrast agent.

Our goal in this research is to develop new imaging methods for cancer diagnostics and treatment monitoring. We are working on the following methods:

- ***Carbon MRI*** to check how your body processes lactate, a substance produced during breakdown of sugar for energy.
- ***Deuterium Metabolic Imaging (DMI)*** to check how your body processes glucose, a sugar labelled with a naturally occurring form of hydrogen.
- ***Sodium MRI*** to check the distribution of naturally occurring sodium in tissue.

We need the help of healthy volunteers to establish what is considered "normal." We also seek healthy individuals with a genetic predisposition to cancer but without active cancer. Volunteers undergo the same procedure as patients, allowing us to compare images and gain insights into the disease process. Your participation plays a crucial role in advancing our understanding and improving medical care.

Why have I been invited?

You have been invited to join this study based on your doctor's observation of a genetic predisposition to cancer.

Do I have to take part?

No, it is up to you to decide. We'll discuss the study with you and provide an information sheet. We'll ask you to sign a consent form to show you have agreed to take part. You're 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.

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

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

If you're a man, we'll ask you to use contraception for two weeks post-imaging. We'll chat 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, when you arrive for your planned scan, we will carry out certain study procedures. We anticipate your visit will take up to **two and a half hours**.

Consent Process:

- If you decide to participate after reading this information sheet, you'll be asked to provide your informed consent.
- You can consent to have one, two, or three different MRI scans (i.e. DMI, Sodium MRI or Carbon MRI). Opting out of one won't affect your participation in others.
- You might need to fast for **up to six hours** before your scan. This is optional and not a must for the study.

Appointment Booking:

- Your MRI scan will be scheduled either at the Department of Magnetic Resonance Imaging and Spectroscopy (MRIS Unit) or the Wolfson Brain Imaging Centre (WBIC) in Addenbrooke's hospital (map **page 16**).

Safety Checklist:

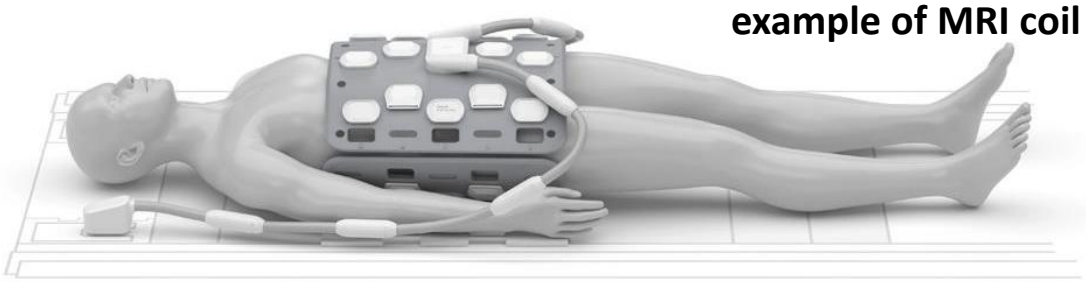
- Please remove metal items before the scan.
- Before the MRI scan, a qualified team member will go through a safety checklist with you.
- We may perform some health checks to ensure your well-being, for example finger prick glucose test, blood pressure, heart rate, oxygen level and temperature.

What will happen if I take part?

MRI Scans:

- You'll be guided to the MRI scanner and asked to lie on a movable bed. We will place your head, torso or abdominal inside a coil which is used to send and receive radio waves that interact with the body's tissues.

example of MRI coil



- The radiographer will operate the scanner from the control room, with constant observation through a two-way intercom.
- Expect to lie still for up to **60 minutes**.
- For Hyperpolarised Carbon MRI, we'll place a tiny tube in your vein for **an injection of pyruvate** just before the scan.
- For DMI, we'll either give you a small cup of **labelled glucose drink** 75 minutes before the scan or we'll place a tiny tube in your vein for **an injection of labelled glucose** just before the scan.
- For Sodium MRI, you'll only have a scan.
- You can find more information about the scans on **page 15**.

What will happen if I take part?

Repeat Scan and Database Participation:

- You may be invited for up to five repeat scans within 6 months – this is **optional**.
- You won't have more than 3 pyruvate injections, more than 3 glucose injections and more than three glucose drinks during your participation in the study.
- We'll offer you the choice to be on a research database for future study invitations; it's entirely up to you.

Optional Blood and Urine Sample:

- With your agreement, we may take **a small blood and urine** sample (two tablespoons) for research. This is optional.

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

What are the possible benefits of taking part?

While there won't be a direct benefit for you, your participation helps advance non-invasive ways to diagnose and monitor diseases, supporting future research and clinical projects.

Reimbursements

We're happy to cover travel and parking expenses related to your study participation. As a token of gratitude, you'll receive a thank-you voucher for any inconveniences.

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

MRI:

- Our MRI scans are safe and don't involve X-rays or radioactivity.
- Some of the equipment used in this study is meant for research, **not routine diagnosis**, but everything is considered safe for human use.
- 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.
- The MRI system is **noisy** but we provide headphones and earplugs.
- You're always visible and can communicate with the staff during the scan.

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

Deuterated Glucose Drink:

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

Cannulation:

This safe and routine procedure involves a small tube in a vein just for the scan. It can cause some **discomfort** and very rarely can lead to **infection**. Some people may experience **bruising** at the site where the cannula is inserted, but this should hopefully be minimal and disappear after a few days.

Labeled Pyruvate Injection:

Labeled pyruvate injections have shown no significant safety issues. It contains a natural, stable isotope of carbon. Injection-related side effects, such as **flushing, feeling hot, metallic taste or dizziness**, are rare, mild, and short-lived. We're equipped to manage any unexpected reactions.

Deuterated Glucose Injection:

Glucose injections are generally safe because glucose is a natural substance that the body can easily process. It is used in medical tests like the glucose tolerance test.

Incidental Findings:

Your scans **are not** for diagnosis but may reveal unexpected things. If we find something important, we'll discuss it with you and your GP. It may mean early treatment but could affect employment and insurance. If you don't want calls in such circumstances, we can't proceed. Your rights remain unaffected.

What happens at the end of the study?

After the study, we'll examine the images and compare them with blood results. This helps us learn more about how our bodies work and figure out the best ways to use MRI scans for diagnosis.

What if there is a problem?

If you have any concerns about how you have been treated or any potential issues, we are here to help. Our contact details are on **page 14**. And if things still are not quite right, you can make a formal complaint through the NHS Complaints Procedure (page 14).

Who will have access to the scans and results?

All the information and pictures we gather in the study will be kept private, following standard medical confidentiality rules. The images will be stored securely, and only the study team will have access to the non-anonymous scans and data.

Will my taking part in the study be kept confidential?

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

Will my GP be informed?

We won't tell anyone you're in the study unless you say it's okay. Still, we suggest letting your GP know about any unexpected findings, just to keep everyone in the loop.

What will happen if I do not 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 impact your future healthcare. If it's okay with you, we'd like to keep using the data and samples (with no personal information) up to the point you decide to step out.

Are there compensation arrangements if something goes wrong?

Don't worry, 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.

How will we use information about you?

For our research, we'll use some information from you and your medical records. The team will use this data to carry out the research properly, but rest assured, your personal details won't be visible to those who don't need to know. We'll assign a unique code to your data, keeping everything about you safe and secure.

After the study ends, we'll keep some data for result checks. Our reports will be written in a way that protects your privacy, making sure no one can figure out you took part in the study.

What are your choices about how your information is used?

You can step back from the study anytime, without giving a reason, but we'll keep information about you that we already have.

We need to manage study records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

You have a say in whether your samples, data, and information are used for future ethical research – feel free to agree or disagree as you see fit.

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

You can visit the following websites:

Health Research Authority:

www.hra.nhs.uk/information-about-patients

Cambridge University Hospitals NHS Foundation Trust:

https://www.cuh.nhs.uk/patient-privacy

or email the Data Protection Officer at: cuh.gdpr@nhs.net

University of Cambridge:

https://www.medschl.cam.ac.uk/research/information-governance

or email the Information Governance team at: researchgovernance@medschl.cam.ac.uk

What will happen to my samples?

We'll label all your samples with a special code to keep track of them, but your identity stays private, known only to our core research team. We'll keep your samples safe in a secure University lab until we process them. We'll analyse your blood for certain molecules and compare the results with your MRI scans. Once we finish the analysis, we'll respectfully dispose of the blood samples.

What will happen to the results of the study?

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.

If you agree, we might share pseudonymized data with collaborators in similar studies, keeping your privacy intact. Additionally, 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.

Who has reviewed the study?

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

Contact details for further information

If you have any further questions, you can contact the study team during office hours (9 AM to 5 PM).

If you're unwell, feel different, end up in the hospital, or visit the emergency department, please reach out to the study team.

Telephone: **01223 256989** or **01223 767926**

Email: 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

PALS (Patient Advice and Liaison Service):

Telephone **01223 216756**

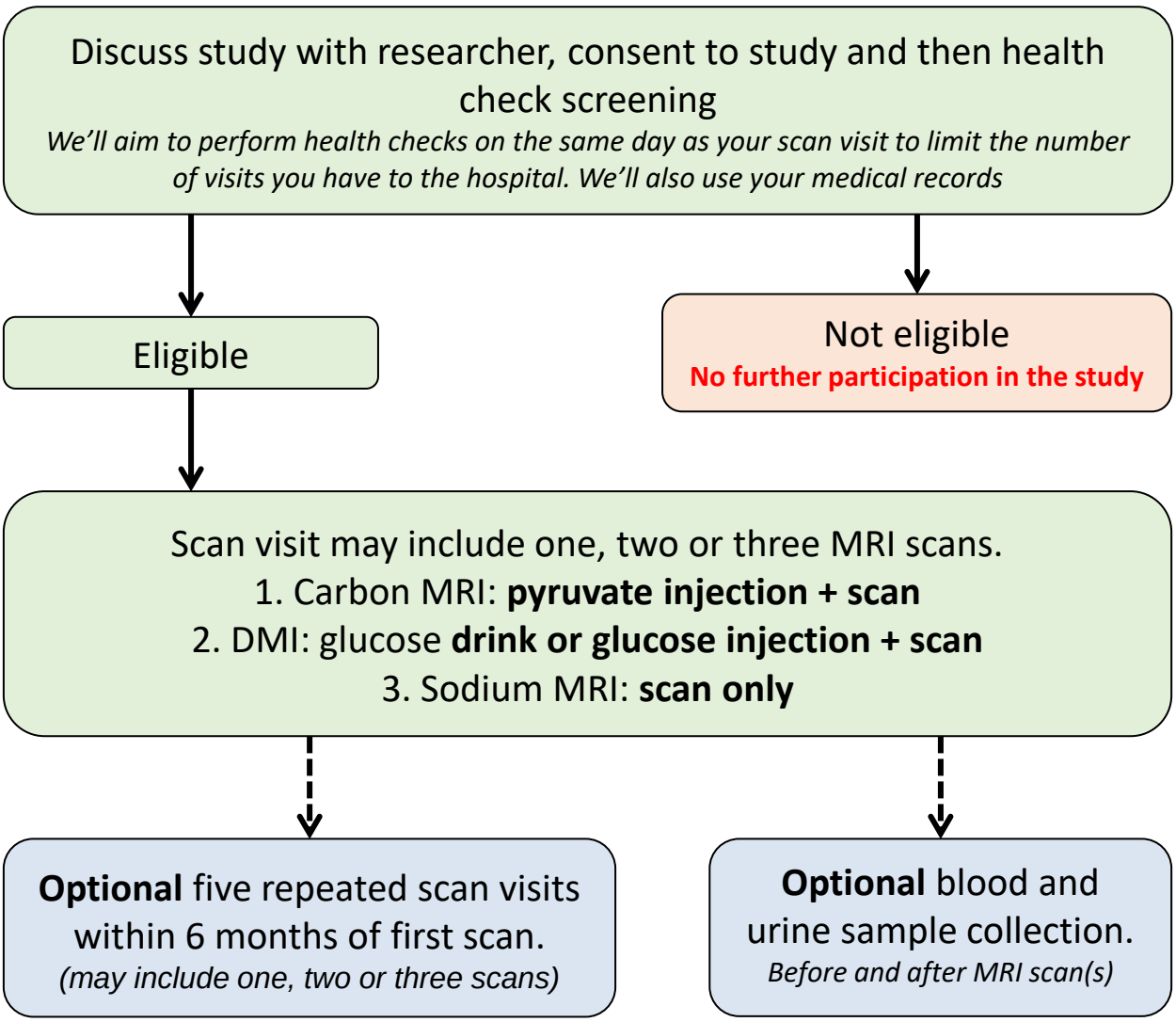
Email cuh.pals@nhs.net

Thank you for thinking about joining the study. If you need more information, just reach out – we are here to assist.
A copy of the consent form will be provided for you.

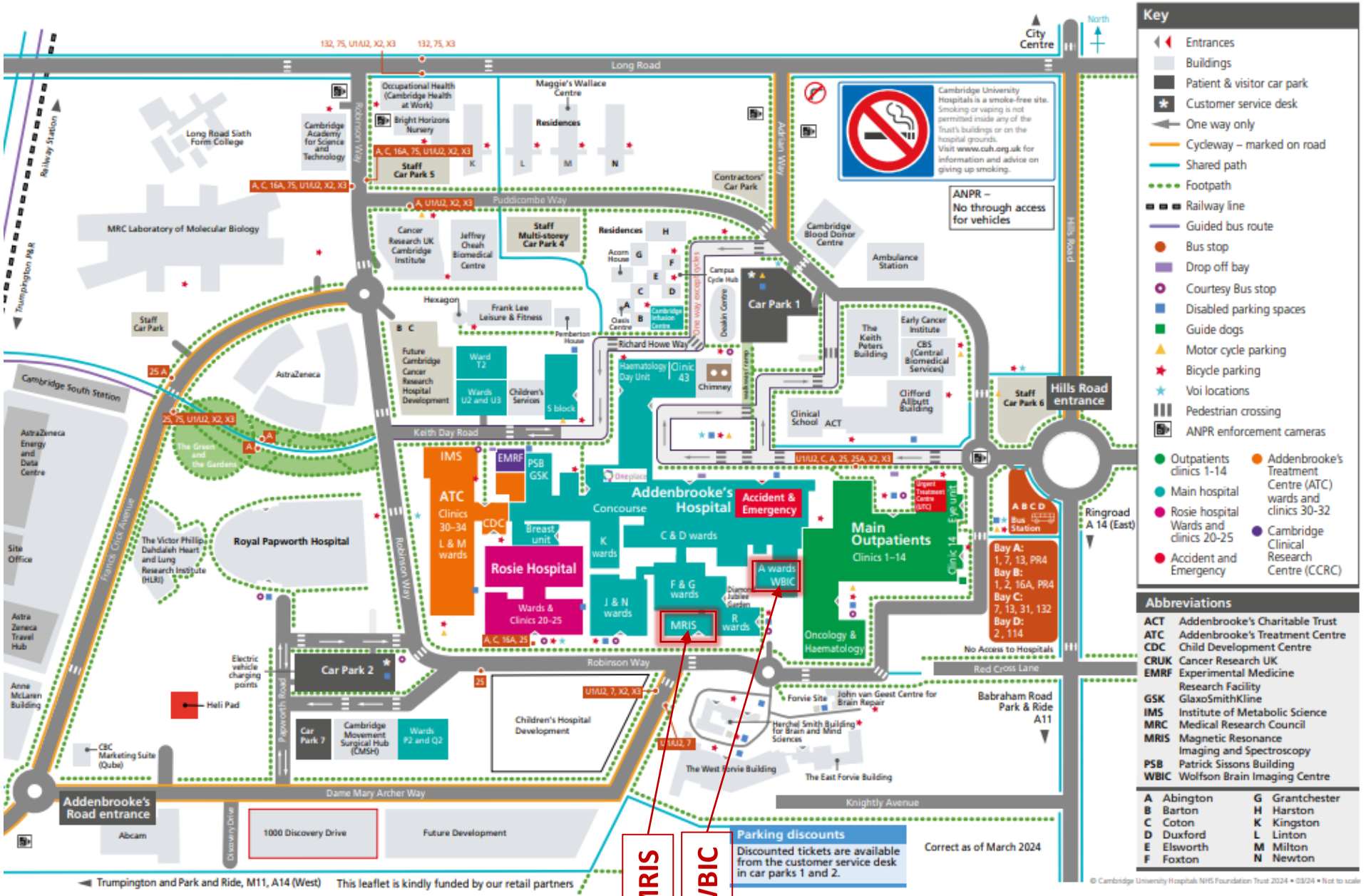
Additional information

If you're up for two scans like Sodium MRI and Carbon MRI, we'll try to do them during the same visit. If it's three scans, we'll chat with you about whether to do them together or separately, considering your time and availability. If it's multiple scans in one visit, we might do both the pyruvate injection and deuterated drink. For all three scans, expect to be in the department for about three and a half hours, but we can discuss and agree on the best plan for you.

Study flowchart



Public entrance points



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

- Outpatients clinics 1-14
- Main hospital
- Rosie hospital Wards and clinics 20-25
- Accident and Emergency
- Addenbrooke's Treatment Centre (ATC) wards and clinics 30-32
- Cambridge Clinical Research Centre (CCRC)

Abbreviations

ACT	Addenbrooke's Charitable Trust
ATC	Addenbrooke's Treatment Centre
CDC	Child Development Centre
CRUK	Cancer Research UK
EMRF	Experimental Medicine Research Facility
GSK	GlaxoSmithKline
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

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