

ENDURE Imaging Sub-Study Flowchart (for inclusion with Core Study Information Leaflet)

<p>ENDURE</p> <p>Understanding beta cell disorders through the study of rare genotypes</p>	<p>Sub-Study:</p> <p>Imaging</p>
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You are eligible to take part in the Imaging Sub-Study, which involves you having an MRI (Magnetic Resonance Imaging) scan.

If preferred, the MRI scan can be arranged as a separate visit to the Core Study visit.

Please read the ENDURE Core Study information leaflet **and** the information overleaf. This will provide information about the MRI to help you decide whether you want to take part in the Imaging Sub-Study.

What will happen during my research appointment?

The research visit will take place at the NIHR Exeter Clinical Research Facility and the Mireille Gillings Neuroimaging Centre (MGNC), which are both located at the Royal Devon and Exeter Hospital in Exeter, England.

What does this involve?	Are there any risks?
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Arrive at Clinical Research Facility.

Give consent to participate.

15-20 mins

At your visit, a member of the ENDURE research team will discuss all aspects of the Imaging Sub-Study with you.

You will have the opportunity to ask questions and when you are happy that you understand what is involved, you will be asked to complete a form giving your consent to participate in the Imaging Sub-Study.

No.

Participation is entirely voluntary, and it is up to you whether to join the study and you can withdraw at any time without giving a reason.

Magnetic Resonance Imaging (MRI) scan

up to 60 mins

For your MRI scan at, you will be asked to change into a gown provided and lie still in an MRI machine (a cylindrical tube/tunnel) for up to a **maximum** of 60 minutes.

You can ask for breaks when and if required.

This is a routine, safe, NHS procedure for which details can be found here: www.nhs.uk/conditions/mri-scan/

We will focus on taking images of your body to measure organ size and look at fat distribution.

Please read the information overleaf.

Prior to making your MRI appointment, you will be asked to complete an MRI Safety Checklist Screening Form to assess your safety in the magnetic environment.

A qualified researcher will monitor you closely throughout the whole MRI scan.

A member of the research team will make sure that you are comfortable before you leave the research facility.

Information about the Imaging Sub-Study

Why am I being invited for the Imaging Sub-Study?

You have been invited into the Imaging Sub-Study because you have either been diagnosed with a genetic change that alters insulin production/secretion, or you are a 'healthy control'. We wish to use images from an MRI scan to compare if the body works differently in people with this specific type of genetic change compared to people without this condition.

What does participation in the Imaging Sub-Study involve?

You will be able to discuss the Imaging Sub-Study with a member of the study team and ask any questions you have.

You will be asked to sign a consent form to say you agree to take part in the study and for your samples and research data to be gifted to us for research purposes (please see the consent statements at the end of this document).

What is an MRI Scan?

An MRI scan involves taking images of your body in a special machine (the MRI scanner). The MRI scan is a standard procedure in normal healthcare. It is painless, non-invasive, and does not involve radioactivity. For the scan(s) you will lie on the scanning table and have to keep still during this time. The scan takes place inside an enclosed space, but you will be able to talk to the people who do the scan (radiographers) during this time, and you can listen to relaxing music.

What will happen to my samples and data from the Imaging Sub-Study?

To include you in the Imaging Sub-Study, the Mireille Gillings Neuroimaging Centre (MGNC) (University of Exeter), which relies on NHS systems and procedures to support this research, will need to store information about you and your imaging scans in paper or electronic format. This information will typically include a signed copy of your consent form, your unique study ID code, demographic information such as your date of birth, age, sex, weight, and any study-specific information. The MRI scans and information will be temporarily stored on the Royal Devon University Healthcare NHS Foundation Trust (RDUH) NHS system prior to storage on the University of Exeter storage platforms. The imaging scans and information may be viewed by staff from the RDUH NHS, the University of Exeter and regulatory authorities to support the conduct of the study.

To ensure correct identification prior to your MRI scan, a "scan request" form is required for the MGNC to conduct the imaging scan. The "scan request" form, which contains your name, date of birth, address, and some relevant medical information, will be sent to the MGNC through an encrypted process. In case of an unlikely medical emergency, the MGNC will hand over relevant information, including personal identifiable data and clinical and study details, to the NHS emergency services.

Are there any risks or benefits associated with MRI scans?

The MRI scanner uses a strong magnet. To reduce risk, before the MRI scan, we will ask you to complete an MRI Safety Checklist Screening Form to check that you do not have any metal inside your body, such as joint replacements, implants, or other objects. Due to being in a confined place some participants may experience anxiety, but this quickly reduces after coming out of the confined space. You can ask at any time to stop the scan and come out the MRI scanner.

Do I have to take part in this Imaging Sub-Study?

No, it is entirely up to you to decide whether or not to take part in the Imaging Sub-Study. You are free to withdraw at any time without giving a reason. Participation in the ENDURE study will not affect your routine health care.

Imaging Sub-Study Consent Statements

You will be asked to complete a form to give your written consent to participate in the ENDURE study.

You will also be asked to confirm the Imaging Sub-Study-related consent statements given below. These are in addition to the consent statements for the Core Study that apply to all participants.

Consent statements for the Imaging Sub-Study

- I have been invited to take part in the Imaging Sub-Study.
- I have been given the ENDURE Core Study information leaflet and the Imaging Sub-Study Flowchart. I have had the opportunity to ask questions and these have been answered fully.
- I agree to:
 - have an appointment(s) as detailed in the Imaging Sub-Study Flowchart.
 - have an MRI scan (as detailed in Imaging Sub-Study Flowchart) at the Mireille Gillings Neuroimaging Centre (University of Exeter).
 - relevant sections of my medical notes and data collected during the study being accessed by responsible individuals from the University of Exeter, or the appointed service providers and NHS Trusts, or regulatory authorities, where it is relevant to my taking part in the research. I give permission for these individuals to access my records.
 - my data being stored for the duration of the study.
- I understand that:
 - data collected during my participation in the Imaging Sub-Study will be stored electronically on secure systems, and in secure paper formats, by the Mireille Gillings Neuroimaging Centre (University of Exeter).
- I agree to take part in the ENDURE Imaging Sub-Study.