



INFORMATION LEAFLET

UK Biobank Repeat Imaging Assessment Visit

We would like to invite you to take part in the UK Biobank's repeat imaging study. Before you decide, it is important that you understand why the study is being done and what taking part involves. Please take time to read this information sheet and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please contact us.

What is the purpose of this study?

It involves taking a repeat set of images (scans) of your brain, heart, tissue and bones, so that scientists can study your internal organs in detail. This will help research into a wide range of diseases, including cancer, heart disease, dementia, diabetes, stroke and arthritis.

We aim to scan at least 60,000 people over the next few years as part of this repeat imaging study.

Why have I been invited to take part?

We have invited you to take part in this repeat imaging assessment because you have already attended an imaging assessment with us. This invitation is not based on any other information that we have collected about you, either at your first imaging assessment or afterwards. Combined with other information you have provided, the scans will create a health resource of worldwide significance for many years to come.

Even though you were eligible to take part in the first imaging assessment, we will need to complete a new eligibility check for the repeat imaging study given that your health and lifestyle may have changed since that first assessment undertaken a few years ago.

As you may recall from your first visit, all of the scans are safe and painless. The scanners are similar to those used routinely in the NHS. However, since MRI scans involve the use of a magnet, you may not be able to take part if you have an electrical implant (for example, a pacemaker) in your body or metal in certain parts of your body, or if you have had an accident where metal may have entered your body.

If you have had recent surgery, you will be able to take part six weeks after your operation. You will not be able to take part if you have medical problems that make it difficult to carry out the scans (for example, severe hearing or breathing problems, tremors or very restricted mobility).

If you would like to take part but think you might not be eligible to do so, we would like you to contact us so that we can check this for you.

Do I have to take part in this repeat imaging assessment?

No; while we are keen for every invited participant to contribute, it is entirely voluntary. We do understand that you may not be able or wish to help, and this decision would not affect your ongoing relationship with UK Biobank. If now is not a good time for you to take part, but you might be interested in the future, there are several options: you can contact us at a later stage when it is more convenient, you can call our Participant Resource Centre to let us know, or if you were invited by email, you can follow the decline link in your email invitation and select “not now but maybe later”.

What does taking part in involve?

During the imaging visit, which lasts 4-5 hours, our centre staff will take detailed MRI images of your heart, abdomen and brain as well as a carotid artery ultrasound of the blood vessels in your neck and a scan of your bones (a DXA scan). They will also take some physical measures, such as your height, weight and blood pressure, and samples of blood and urine. We will ask you to provide some more information about your health and lifestyle via a touchscreen questionnaire.

Will I find out the results of my scans?

You will receive a note of some standard measurements at the end of your visit (blood pressure, weight, body mass index, waist circumference, percent body fat and lung function, if measured) but you will not receive the results of your imaging scans. These scans are set up to collect research information not to diagnose disease, and they are not systematically reviewed to diagnose disease.

We will not routinely feedback your imaging results to you, your GP or anyone else – this is in accordance with the consent you provided when you agreed to take part in UK Biobank. However, if a potentially serious abnormality is noticed during your scans, we will write to tell you and your GP. A potentially serious abnormality is considered to be one which may have a major effect on how your body functions or on your quality of life, or which could be life-threatening. Please read to the end of this information sheet to find out more about this feedback.

To take part, you must be willing to agree that we can tell both you and your GP if we do notice a potentially serious abnormality on one of your scans. If we do not contact you and your GP, it does not necessarily mean that you have no abnormality but simply that nothing abnormal was noticed when the scans were being done.

What are the possible BENEFITS of taking part?

There are no direct benefits to you as an individual, although some people may regard having feedback about a potentially serious abnormality (if one is noticed during the scan) as a benefit. However, others may regard this as a risk if the abnormality turns out to be nothing serious (because of the short-term anxiety this information may cause).

The information about you from the scans and other assessments will help scientists to better understand how a wide variety of diseases develop and to find new ways to prevent and treat them.

What are the possible RISKS of taking part?

Your repeat imaging assessment visit should not cause you any harm.

We have chosen scans and other physical measures that are safe, painless, relatively quick and comfortable.

The MRI scanners use powerful magnets and we take great care to prevent magnetic objects from entering the MRI room. Before you enter, we will ask you some questions to confirm your suitability for the scans. The low-energy DXA scan involves a small dose of radiation - the same amount as a standard chest X-ray or about one week's worth of natural background X-rays. You may feel some discomfort when you have blood taken, although our health research assistants are specially trained to minimise this.

How will you keep information about me confidential?

We place great value on our participants' confidentiality and have strict measures in place to protect your confidentiality, which should prevent identifiable information from being used – inadvertently or deliberately – for any purpose other than to support this study:

- We do not include any details that will identify you in any information or samples we provide to researchers. Furthermore, all the brain scans are 'defaced' so that researchers using these scans will not be able to tell your identity from these data.
- We keep any information that might identify you (such as your name and address) separately from other information about you in our database.
- We use advanced computer security technologies to prevent unauthorised access to the computers that hold your personal information.

- We operate quality and information security management systems that support the collection, processing, storage and analysis of biological samples and data for research into genetic and environmental factors that impact on human health and disease. The systems are audited and certified by the British Standards Institute (BSI) to ISO 9001 and ISO/IEC 27001 respectively. You can view the status of our certifications for the various sites by searching for 'UK Biobank' at this link <https://www.bsigroup.com/en-GB/validate-bsi-issued-certificates/>
- We also follow the guidance contained in the UK Government's ten cyber security steps and have achieved the UK Government's Cyber Essentials Plus accreditation.
- We restrict access to personal information as much as possible, and all research staff working for us sign confidentiality agreements as part of their employment contracts.

What will happen to the information and samples I give?

The information obtained in this study will be treated in exactly the same way as all of the other data that we have collected about you and will be stored securely by UK Biobank for many years.

The way in which UK Biobank collects, shares and uses your information is explained in our privacy notice for participants which is on our website at: www.ukbiobank.ac.uk/explore-your-participation/basis-of-your-participation. This includes an explanation of the way in which we protect your data and remove any personal identifiers before making data available to researchers.

UK Biobank data is provided only in a **de-identified** form (such that no participant can be identified from their data or samples) to approved researchers for all types of health-related research that is in the public interest. All researchers, whether in universities, charities, government agencies or commercial companies, and whether based

in the UK or abroad, are subject to the same application process and approval criteria.

We will put the results from all of these studies back into our database for other researchers to use. Scientists must make public the results of all research based on the resource so that everyone can benefit from it. You can find details of research that is being conducted using the UK Biobank resource and related publications on our website.

Who has reviewed this study?

All of the research conducted by UK Biobank is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by the North West – Haydock Research Ethics Committee, ref. 16/NW/0274 and 21/NW/0157.

What should I do if I am interested in taking part?

First, make sure that you fully understand what taking part involves by reading this information sheet carefully. Then please phone our Participant Resource Centre free of charge on: **0800 0 276 276 (Monday to Friday 9am to 5pm)**.

During this call, you will be able to ask us any questions that you might have. We will also ask you some questions about your medical history to check your suitability for the scans.

If you are eligible to take part, we will arrange an appointment for you. Appointments are generally available from 8am to 2.45pm, Monday to Sunday, and last for four to five hours.

We will send you a letter confirming your appointment and giving directions to the assessment centre. If you have provided us with an email address and mobile phone number, we will also contact you to remind you about your appointment a few days before your visit.

If anything is not clear, or if you would like more information before calling us, you can read more and view videos of the participant journey through our imaging centres at <https://www.ukbiobank.ac.uk/get-involved/repeat-imaging-project>. If you still need help, please phone us on **0800 0 276 276** or email us at ukbiobank@ukbiobank.ac.uk.

Thank you for your continued support of UK Biobank.

Without the help of our participants, we would not be able to continue to create such an invaluable resource for health research.



FURTHER USEFUL INFORMATION

What is UK Biobank?

UK Biobank is a large-scale biomedical database and research resource that contains genetic, lifestyle and health information from half a million UK participants, of which you are one.

UK Biobank's database, which now also includes genetic data for all participants and the heart, body, brain, neck artery and bone scans from over 85,000 participants, is globally accessible to approved researchers who are undertaking health-related research that is in the public interest.

UK Biobank's research resource is a major contributor to the advancement of modern medicine and treatment, enabling better understanding of the prevention, diagnosis and treatment of a wide range of serious and life-threatening illnesses – including cancer, heart disease and stroke. While taking part in UK Biobank is not intended to help you directly, it should give future generations a much better chance of living their lives free of diseases that disable and kill.

UK Biobank is generously supported by its founding funders the Medical Research Council and Wellcome, as well as the Department of Health and Social Care, the British Heart Foundation and Cancer Research UK. We also seek additional funding from government, charitable, commercial and philanthropic sources to help enhance and enrich UK Biobank for researchers. Full details are published on our website (<https://www.ukbiobank.ac.uk/learn-more-about-uk-biobank/about-us/our-funding>)

Why do you want to scan me?

Taking images of organs inside the body (such as the brain and heart) as well as the surrounding tissues and bones allows scientists to study how the structure and function of the body's organs are related to the development of disease.

By collecting scans at different time points, scientists will also be able to study changes that occur in the body's organs over time.

The combination of these images with other information already collected about you will provide new and important information for health research on a wide range of diseases.

Why have you invited me?

You have been invited simply because you have previously attended an imaging assessment with UK Biobank. This invitation is not based on any other information that we have collected about you, either at your first imaging assessment or afterwards. We aim to scan at least 60,000 people over the next few years as part of this repeat imaging study.

Can I claim travel expenses?

Your repeat imaging assessment will take place at the centre which you attended for your first imaging assessment, to make sure that your repeat set of images are directly comparable to your first images.

We appreciate that some participants live a considerable distance away. You can claim the cost of travel to the assessment centre by public or private transport, using the claim form that we will provide you with at the end of your visit. Please keep your travel receipts and attach them to the claim form.

Train and other public transport (i.e. bus, tram, Metro or underground)

For train travel, please keep in mind the following:

- Please buy standard tickets (i.e. not first-class).
- Booking in advance usually means that you get the best value tickets. Where possible, please avoid booking open return tickets as these tend to be the most expensive.
- Buying split tickets may reduce the overall price of your fare. See www.splitticketing.com to find out more.

Private transport (car, motorcycle or bicycle)

We will reimburse you for your travel to and from the assessment centre on a 'per mile' basis. Current mileage allowances can be found in our participant travel expense claim policy at www.ukbiobank.ac.uk/travel-expenses-policy and we will advise you about this when you telephone us to enrol in the study.

Car parking

There is free parking at our centres. If you need to park elsewhere, you can claim car parking costs (but not fines). We can provide advice about nearby electric vehicle (EV) charging points when you phone us to enrol in the study.

Tolls and tunnel fees

Tolls and tunnel fees may be claimed.

Travel companions

If you need someone to help you during the journey, you can also claim travel expenses for a companion. There is some space with free Wi-Fi where your companion can wait in the reception area. However, it can get busy and the chairs are only adequate for sitting for short periods, so we recommend that your companion plans to do something outside of the centre while you are having your assessment. We will advise you about this when you phone us to enrol in the study.

Please keep your travel receipts and attach them to your claim form which we will give you at the end of your visit.

What happens DURING the repeat imaging assessment visit?

You can view videos of the assessment visit at <https://www.ukbiobank.ac.uk/get-involved/repeat-imaging-project>. The assessment will take four to five hours and will involve the following:

First steps

- A radiographer will ask you the same questions that you answered when you made the appointment. This is to double-check that you are able to have all of the different types of scans.
- You can ask any questions that you might have, and we will then ask you to complete and sign a consent form. This tells us that you agree to be scanned, and that you understand the nature and purpose of the imaging process and any potential implications.
- We will show you to a private cubicle where we will give you special, loose-fitting clothes to change into. You will not need to remove your underpants (but please do not wear underwear containing Lycra, Spandex or any sort of metal or jewel embellishments). We will ask anyone wearing a bra to remove it as it may contain metal.
- We will ask you to leave any loose metal objects (such as money, credit cards, keys, pens, mobile phones, jewellery, watches, hair pins, metal dentures, hearing aids and spectacles) in one of the secure lockers. We will also ask you to remove any skin patches (for example, nicotine or pain relief patches) during the assessment visit, so you might want to bring a replacement patch with you.
- If you have a monitor fitted (such as a glucose monitor), you will need to remove this yourself for the duration of the imaging assessment (up to five hours) as our staff cannot do this for you. You will be welcome to use our facilities (e.g. a private room, sharps bin and dressings) to do this. Please seek professional advice prior to your appointment if you are unsure that you can safely remove your monitor for this time period.

- We may ask people with chest hair if a staff member can shave a small section of it. This is so that we can place electrical leads attached to sticky pads on the skin for an electrocardiogram (ECG - an electrical recording of the heart) and for the heart MRI scan.

MRI (magnetic resonance imaging) scans

- These use painless magnetic fields to take detailed pictures of the inside of the body (such as organs, tissues and bones). We would like to take two scans, involving two separate scanners, each taking about 30 minutes:



Image of an MRI scanner

Brain MRI scan.

- This will provide information about the structure and function of the brain; for example, which parts of the brain are important for carrying out certain tasks and how different parts of the brain are connected.

Heart and body MRI scan.

- This will provide information on the size of the heart chambers and blood vessels, and changes in the size of the heart as it beats. It will also provide detailed information on the amount and distribution of fat in the body.
- The MRI scanner is a large cylinder with a tube running through the middle which is open at both ends. The scanners are similar to those used in the NHS but are a little wider (about 70 cm/27 inches in diameter) so that they are more comfortable. We will show you into a room containing one of the two MRI scanners. We will ask you to lie flat on your back (with your legs supported) on a comfortably padded table that gently glides you into the scanning tube. You will be given a pillow on the MRI heart scanner, but will need to be able to lie flat without a pillow for the MRI brain scan.

- The MRI scanner is controlled by a computer which is in an adjacent room. A specially trained radiographer will operate the MRI scanner. They will be watching you through a window throughout the scan, and you will be able to talk to them through an intercom.
- Whilst there are no known long term negative effects on hearing as a result of MR imaging some of the UK Biobank MRI sequences will make loud noises, above 85Db, for a short period of time. We provide high quality earplugs that reduce noise exposure to safe levels and ensure that we adhere to all relevant health and safety regulations.
- You will have a hand-held buzzer so that you can alert the radiographer if you have an issue or would like to stop the process at any time.
- For the brain MRI scan, a helmet-like covering will be placed over your head. This allows a close detailed examination of your brain. A mirror in front of your face will allow you to view images shown on a screen behind you.
- For some MRI scans, you will be asked to perform certain tasks. For example, we will show you something on a screen (e.g. facial images or shapes) during the brain scan. We will ask you to hold your breath several times during the heart scan.

Neck ultrasound scan

This uses ultrasound (high-frequency sound waves) to produce images of the blood vessels on either side of the neck. These images will help scientists study any narrowing of these major blood vessels. The neck ultrasound scan takes about 10 minutes.



Image of a neck ultrasound

- We will ask you to lie face-up on a firm table. We will apply a clear water-based gel to your neck and then place a hand-held probe against your skin and move it up and down your neck.
- We will ask you to tilt or turn your head as we move the probe over the entire length of both sides of your neck.
- The probe will move over the skin of your neck but will not touch your face or other parts of your body.

DXA (dual-energy X-ray absorptiometry) scan

This uses low-energy X-rays (the same amount as about one week's worth of natural background X-rays) to measure bone density throughout the body. Detailed pictures of the spine, hips and knees will help scientists to study diseases like osteoporosis (thinning of the bones) and arthritis. The DXA scan takes about 20 minutes.



Image of a DXA scanner

- We will ask you to lie flat on your back (without a pillow) on a firm table while the arm of the scanner passes over you (see picture) to take X-ray images of your bones. We will ask you to lie in various positions so that the scanner can take images of different parts of your body.

Autorefraction

A handheld device will be used to take these measurements (see image); this has a forehead rest to help stabilise the device but there will be no contact with your eye.



Image of autorefraction process

- These measurements are performed on both eyes in a darkened room, and take about two minutes.
- You will be asked to remove your glasses (if worn) and ideally to remove any contact lenses worn (although this is not essential).
- You will be asked to focus on an image while the measurements are taken.

Optical coherence tomography (OCT)

These measurements will be taken using an OCT machine, similar to the machines used by opticians.



- This measurement is performed on both eyes in a darkened room, and takes less than five minutes.
- You will be asked to remove your glasses (if worn) but you can wear contact lenses. You will be asked to place your head against the device's forehead and chin rests to keep it stable while the images are taken. The device will be positioned in front of your eye (see photo) but there will be no contact with your eye.
- You will be asked to focus on the centre of a cross. There will be a flash of light as the images are taken.

Other assessments

We would also like to take some more samples, ask questions and take measurements, similar to your first visit to UK Biobank several years ago. This will allow scientists to take account of any changes in health and lifestyle since then and to obtain some new information about you.

We will ask you to do the following:

- Give another small sample of blood (about three tablespoons) and urine for long-term storage and analysis.
- Answer questions on a touchscreen computer about your health, lifestyle and diet, memory, work and family history.
- Have measurements of your blood pressure, pulse rate, arterial stiffness, height, weight, body fat, grip strength and lung function taken. You will also have an electrocardiogram (ECG) to measure the electrical activity of your heart

Do I need to have all the measurements taken?

You need to be willing to take part in all of the scans before you make an appointment.

You do not have to have all the physical measures, give a blood or urine sample if you do not want to. Also, if you feel uncomfortable answering certain questions, you do not need to answer them.

What if something suspicious is seen during my scans?

The scans we do are not intended to diagnose disease. They are not designed to find any particular abnormalities and will not be routinely analysed by doctors or other specialists. The radiographers who do the scans will be looking at the images to make sure of their quality, rather than looking for evidence of any health problems.

However, abnormalities can show up during the scanning process on scans taken for research purposes. Most of these are no cause for concern but if the radiographer does happen to notice a potentially serious abnormality while taking the scan, they will refer the scans after your visit to a specialist doctor (radiologist) for review.

If the radiologist agrees that the abnormality is potentially serious (regardless of whether or not it might be treatable), we will write to you and your GP, usually within a few weeks of your visit. Please note that we are not able to provide you or your GP with copies of scans.

We would consider something to be potentially serious if your scans suggested the possibility of a condition which, if confirmed, could have a major effect on how your body functions or on your quality of life, or could be life-threatening.

For example, we would tell you and your GP if we saw an abnormality on one of your scans that looked as though it could be a malignant tumour or another similarly serious condition, such as a large swelling of the aorta (the main artery of the body).

On the other hand, we would not tell you if we saw typical appearances of gallstones, a simple cyst or scarring (e.g., on the lung) as these abnormalities are common in healthy people and not considered serious.

We would also not tell you about something that is clearly related to a health condition that you have already told us about. Finally, we would not tell you about a potentially serious abnormality if it was identified at a later date by researchers analysing the scans.

From our experience so far, about two out of every hundred people taking part in this visit (2%) will have an abnormality that a radiologist agrees is potentially serious and which we will write to you and your GP about. About one in three of these people will turn out to have something serious that they may not have been aware of before, while two in three of these people will turn out to have something non-serious. This happens because something that looks suspicious on one of our research scans can turn out to be something like a benign cyst, an artefact (or technical glitch) of the scanning process, or something that you or your GP already know about (but we do not).

It is important to understand that we will not notice all potentially serious abnormalities. For this reason, if you do not receive any feedback from us about a potentially serious abnormality, you should not regard this as reassurance about your health. It should not stop you from seeing your doctor about any health concerns that you might have.

Please see our website (www.ukbiobank.ac.uk/incidental-findings) for further information about the types of potentially serious abnormalities that we will tell you and your GP about. The radiographers undertaking the scanning are trained in how to report potentially serious abnormalities if detected.

What may happen if I am told about something suspicious on my scans?

Your GP may refer you to specialists for further investigation and treatment.

Some abnormalities found on scans might never have been noticed (especially if they never caused you any problems). Other abnormalities might have come to light weeks, months or even years later. Finding abnormalities on scans can lead to an earlier diagnosis, which can be helpful for some conditions. But sometimes it can lead to unnecessary anxiety, investigations and treatments. Some diagnoses could affect your ability to drive, work or get travel, health or life insurance.

You can only take part in the repeat imaging study if you agree that we can tell both you and your GP if we notice a potentially serious abnormality on one of your scans. If you feel that the anxiety of being told about an abnormality or the disruption to your life caused by further investigations is likely to outweigh any benefit to you, it might be better not to take part in the repeat imaging study.

Our approach to dealing with potentially serious abnormalities on the imaging scans was chosen because it strikes the best balance between:

- maximising benefit (due to the feedback provided to you and your GP about potentially serious abnormalities), and
- minimising harm (due to the unnecessary anxiety and clinical investigations caused by feedback of abnormalities that turn out to be non-serious).

Infection control

We take very seriously the health and safety of our participants and staff alike and put in place strict measures to ensure that our imaging centres are safe. We routinely review our operational practices to minimise the risks to safety and to prevent the transmission of infections.

To help with this, please do not attend your imaging appointment if you have an infection which might affect or be transmitted to those around you, for example a respiratory infection (such as COVID-19, a cold or influenza), vomiting and diarrhoea or shingles.

What should I do if I am interested in attending?

Please let us know if you would like to take part by phoning us free of charge on: **0800 0 276 276 (Monday to Friday 9am to 5pm)**

During this call, you will be able to ask us any questions that you might have. We will also ask you some questions about your medical history to check your suitability for the scans.

If you are eligible to take part, we will arrange an appointment for you at the imaging centre you attended for your first imaging visit. Appointments are generally available from 8am to 2.45pm, Monday to Sunday, and last for four to five hours. Please note that it may be possible to book an appointment up to three months in advance.

If you would like to attend with another UK Biobank participant, e.g. your spouse or a friend, we can arrange this if they are also eligible to attend. Please let our Participant Resource Centre know this when you phone us to enrol in the study.

We will send you a letter confirming your appointment and include directions to the assessment centre. If you have provided us with an email address and mobile phone number, we will also contact you to remind you about your appointment a few days before your visit.

Who do I contact if I have any questions?

If this leaflet does not answer your questions, please:

- visit our website at <https://www.ukbiobank.ac.uk/get-involved/repeat-imaging-project>
- phone us free of charge on **0800 0 276 276** (Monday to Friday 9am to 5pm) for more information; or
- email us at **ukbiobank@ukbiobank.ac.uk**.

If you would like to contact the Principal Investigator, please send a letter to Professor Sir Rory Collins, UK Biobank, 1-2 Spectrum Way, Adswold, Stockport, Cheshire, SK3 0SA, or email **ukbiobank@ukbiobank.ac.uk**

We shall reply to your letter or email promptly in writing, unless you ask us to phone you (in which case, please include your phone number in your letter or email).



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