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INFORMATION LEAFLET

UK Biobank Imaging Assessment Visit

We are inviting you to take part in an important new UK Biobank assessment to help research. It involves taking 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 100,000 people over the next few years. Combined with other information you have provided, the scans will create a health resource of worldwide significance for many years to come. We keep all of the information you give us confidential and store it securely. None of the information, samples or images that we provide to researchers will include any details that can identify you.

We are inviting you to take part in this imaging assessment because you live within a reasonable travelling distance of one of our imaging assessment centres. This invitation is not based on any other information that we have collected about you, either at your first assessment or afterwards.

Taking part is entirely voluntary and will not affect your ongoing relationship with UK Biobank. Please take the time to read this leaflet carefully. It explains why we are asking you to help and what it would involve.

If anything is not clear, or if you would like more information, please phone free of charge on **0800 0 276 276** (Monday to Friday 8am to 6pm and Saturday 8am to 4pm) or email us at ukbiobank@ukbiobank.ac.uk

You can find more information at www.ukbiobank.ac.uk.

Thank you for your continued support.





What is UK Biobank?

UK Biobank is a large, publicly-funded resource that is helping scientists from around the world to improve the prevention, diagnosis and treatment of a wide range of diseases (such as cancer, heart disease, diabetes, dementia, and joint problems). By studying people's responses to questions, physical measurements and samples collected from all 500,000 people in the study, scientists can work out why some people develop particular diseases while others do not.

Their research will help to find new ways to prevent early death and disability. 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 funded by the Wellcome Trust, Medical Research Council, Department of Health and the Scottish Government. It has received additional funding from the Welsh Assembly Government, the British Heart Foundation and Diabetes UK.

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, will allow scientists to study how the structure and function of the body's organs are related to the development of disease.

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.

The scans are for research purposes only. They are not designed to diagnose disease or to detect specific clinical abnormalities. It is important for you to understand that the imaging assessment is not a health check. We will not routinely feedback imaging results to you. However, if we happen to notice an abnormal appearance on one of your scans that we think might be serious, then we will contact you and your doctor. Please read to the end of this leaflet to find out more about this feedback.



Why have you invited me?

We are inviting people who live within a reasonable travelling distance to one of our imaging assessment centres. The high cost of setting up an imaging centre means that we can only open four such centres around the UK. As a result, some people will have to travel further to take part than they did for their original UK Biobank assessment, although we will cover travel expenses.

Invitations are not based on any other information that has already been collected about you.

What scans will you do and why?

Magnetic resonance imaging (MRI). 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: one of the brain and the other of the heart and body (mainly covering the abdomen). The scanners are similar to those used in the NHS, but are a little wider so that they are more comfortable.

- **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.

Neck artery 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.

Dual-Energy x-ray Absorptiometry (DXA) 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.

Am I eligible to take part?

All of these 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 will not be able to take part if you have any metal or electrical implant (for example, a pacemaker) in your body, or if you have had an accident where metal may have entered your body.

If you have had recent surgery, you will not be able to take part for at least six weeks after your operation. You will also 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, or tremors).

Do I have to take part in this imaging assessment?

No, it is entirely voluntary. We do understand that you may not have time or be able to help on this occasion.

What should I do if I am interested in attending?

Please let us know as soon as possible if you would like to take part by phoning us free of charge on:

0800 0 276 276 (Monday to Friday 8am to 6pm and Saturday, 8am to 4pm)

During this call, you will be able to ask us any questions you might have. We will also ask you some questions about your medical history to check your suitability for the scans. You can see this list of questions on our website (www.imaging.ukbiobank.ac.uk), but please do not worry about any technical terms that you do not understand as we will explain these to you during the call.

If you are eligible to take part, you will be able to arrange an appointment during this call. Appointments are generally available starting from 8am to 3.20pm, every day of the week (Monday to Sunday), and last about four to five hours.

We will then send you a letter confirming your appointment, along with directions to the assessment centre. We will also send you an email or text reminder a couple of days before your visit.

Can I claim travel expenses?

We will reimburse the following travel expenses:

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, 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)

A mileage allowance of 25p per mile for car and 9p per mile for motorcycle or bicycle will be paid.

Car parking

There is free parking at the centre. If you park elsewhere, you can claim car parking costs (but not fines).

Tolls and tunnel fees

Tolls and tunnel fees may be claimed.

If you need someone to help you during the journey, you can also claim travel expenses for a companion.

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

What happens DURING the imaging assessment visit?

The assessment will take about 4-5 hours. It will involve the following:

First steps

- A trained member of staff will ask the same questions 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 process and any potential implications.
- We will show you to a private cubicle where we will give you special, loose-fitting clothes to change in to. You will not need to remove your underpants, but we will ask women to remove their bras, as they 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), as well as any skin patches (for example, nicotine patches) in one of the secure lockers.
- We may ask men if a staff member can shave a small section of their chest hair. 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

- You will have two MRI scans, each taking about 30 minutes.
- We will show you into a room that has one of the two MRI scanners. The scanner is a large cylinder with a tube running through the middle which is open at both ends (see picture below). We will ask you to lie down on a comfortably padded table that gently glides you into the scanning tube.

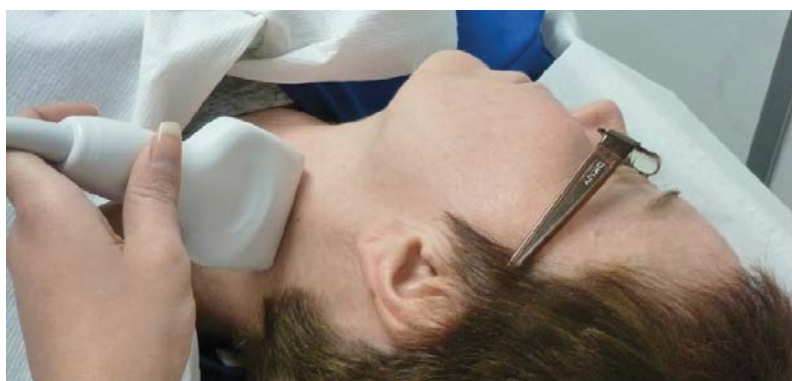


Image of an MRI scanner

- The MRI scanner is controlled by a computer which is in a different room. A specially trained technician will operate the computer. They will be able to see you through a window throughout the scan, and you will be able to talk to them through an intercom.
- MRI scanners are noisy and can vibrate (or judder) a bit. We will give you earplugs to protect your hearing, although most people will still hear quite a lot of noise.
- For the brain MRI scan, a small, open grill-like structure is placed in front of your face. Although it does not touch your face, it is like wearing a party mask and can seem rather odd. This focuses the magnetic field onto you and is important for getting the best pictures of the brain.
- For some MRI scans, you will be asked to do things. For example, we will show you something on a screen during the brain scan, and ask you to hold your breath for a short time during the heart scan.
- You will still be able to talk to the operator throughout the scan, and will have a hand-held buzzer so that you can stop the process at any time.

Neck ultrasound scan

- The neck scan takes about 10 minutes



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 (see picture above).
- 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

- The DXA scan takes about 20 minutes.
- We will ask you to lie on a firm table while an arm of the scanner passes over you (see picture below) 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.



Image of a DXA scanner

Other assessments

We would also like to take some more samples, ask questions and take measurements, very 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 3 tablespoons) and urine for long-term storage and analysis. We may also ask if you would like to provide a stool sample. We will provide you with the kit and instructions separately, so that you can do this at home and bring the sample with you to the assessment centre.
- Answer questions on your health, lifestyle and diet, memory, work and family history.
- Take measurements of your blood pressure, pulse rate, arterial stiffness, height, weight, body fat, grip strength, heel bone density and lung function. You will also have an electrocardiogram (ECG) to measure the electrical activity of your heart.

- We may also ask if you would like to wear a heart monitoring patch for two weeks. This is a water-resistant adhesive patch that is applied to your skin over the heart and which will provide information on heart rhythm. We will give this to you when you visit us, together with a box so that you can return the device to us after the two-week period.

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). Please see the section below for more information about this.

More broadly, 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 them.

What are the possible RISKS of taking part?

Your imaging 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 scans 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. MRI scans involve lying flat in a slightly confined space and a small number of people may find this uncomfortable. However, the scanners we use in this assessment are wider (they are about 70 cm, or 27 inches, in diameter) than those typically used in hospitals, to make sure that you will be as comfortable as possible.

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. (One transatlantic flight exposes you to about four times as much radiation as that from a DXA scan).

You may feel some discomfort when you have blood taken, although our research staff are specially trained to minimise it.

Do I need to have all the measurements?

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 or to give a blood or urine sample if you don't want to. Also, if you feel uncomfortable about answering certain questions, you do not need to answer them.

Do I get any results from the visit?

It is important to understand that the visit is not a clinical appointment or a health check.

We will give you information at the end of the visit about a few of the measurements we take during the assessment (blood pressure, weight, body mass index, waist circumference, percent body fat, heel bone ultrasound and lung function). However, we will not provide any other results or images from the scans.


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 technicians (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 on scans taken for research during the scanning process. 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.

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 out of every 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 don't).

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.imaging.ukbiobank.ac.uk) for further information about the types of potentially serious abnormalities that we will tell you and your GP about.

We are carefully monitoring our processes for reporting potentially serious abnormalities. The technicians doing the scanning have ongoing training about the abnormalities that they notice.

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 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 imaging study.

How are you assessing the effect of telling people about potentially serious abnormalities?

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

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

We will continue to assess how being told about a potentially serious abnormality affects people taking part in the imaging study, as well as the people involved in their care in the NHS. This will allow us to improve what we do and help others doing similar research.

About 6 weeks after we tell you about a potentially serious abnormality, we will contact you to find out what is happening as a result of receiving this information. We will also contact you and your GP about 6 months after your imaging assessment to ask about any investigations and treatment that you may have had.

Who will be able to use my information and samples?

We will store information and samples from your visit (for example, scans and blood results) for many years. The information will be used by approved researchers for medical and other health-related research. This includes scientists working in other countries and in commercial companies.

We will put the results from all of these studies back into our database for other researchers to use. Scientists must also 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 done using the UK Biobank resource and the related publications on our website (www.ukbiobank.ac.uk).

We will never pass your information, samples or test results to insurance companies or employers. Also, we will not allow the police, security services, relatives or lawyers to access your information, unless we are forced to do so by the courts.

How will you keep information about me confidential?

We have strict measures in place to protect your confidentiality. These include the following:

- We do not include any details that will identify you in any information or samples we give to researchers. Further, 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 high-level computer security (for example, firewalls) to block unauthorised access (for example, by hackers) to the computers that hold personal information.
- All of our procedures comply with international standards (ISO 27001) for information security and management. We are externally audited and we comply with the guidance contained in the UK Government’s ten cyber security steps.

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.

Who do I contact if I have any questions?

If this leaflet does not answer your questions, please phone us free of charge on 0800 0 276 276 (Monday to Friday 8am to 6pm and Saturday 8am to 4pm) for more information, or visit our website at www.ukbiobank.ac.uk.

If you would like to contact the person in charge, please send a letter or email to:

Professor Sir Rory Collins

UK Biobank
1-2 Spectrum Way
Adswold Stockport Cheshire SK3 0SA

Email: ukbiobank@ukbiobank.ac.uk

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

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