



# uk biobank

## Brain Health Study

### **Study Information Sheet for Study Partners**

- Your relative/friend is taking part in the UK Biobank Brain Health Study.
- They have nominated you, as someone who knows them well, to join them in the study as their Study Partner.
- We would like to invite you to come to one of our research centres with your relative/friend to support them during the visit and to complete a short questionnaire.
- This information sheet explains what the Brain Health Study is, why we are doing it, and why we would like your help. It will help you decide if you want to take part.
- Please take the time to read this information sheet carefully and discuss it with others if you wish.
- You can find out more about the Brain Health Study on our website at: <https://www.ukbiobank.ac.uk/brain-health-study>.
- If anything is unclear or you would like further information, please phone free of charge on 0800 0 276 276 (Monday to Friday 9am to 5pm) or email us at [ukbiobank@ukbiobank.ac.uk](mailto:ukbiobank@ukbiobank.ac.uk).
- Taking part is entirely voluntary and will not affect your relative/friend's ongoing relationship with UK Biobank.
- Please keep this information sheet to remind you about the UK Biobank Brain Health Study.

## What is UK Biobank?

UK Biobank is a large-scale dataset of biological, health and lifestyle information collected from 500,000 participants, of which your relative/friend is one. Volunteers, aged between 40 and 69 years, were recruited between 2006 and 2010. At recruitment, physical measures were taken together with information about lifestyle and medical history and samples of blood, urine and saliva which are stored for future analysis.

After personal identifying information is removed, the dataset is made available for research that will benefit the public, such as understanding the causes of disease. Researchers all over the world are using UK Biobank data to make scientific breakthroughs and advance healthcare.

We regularly ask our participants to give us more information about their health and to collect additional data, such as scans and blood samples. Sometimes we ask them to wear devices such as activity monitors. This increases the depth of information about our participants and makes the dataset even more important for research. Participants have also given consent for us to access their medical records. This means we can follow their health and well-being throughout their lifetime.

## About the UK Biobank Brain Health Study

The UK Biobank Brain Health Study aims to collect detailed information about the brain health of existing UK Biobank participants. The data we are collecting is designed to help researchers identify different types of brain health conditions, such as dementia and Parkinson's disease.

This will enable research into better ways to diagnose and treat these health conditions for future generations.

Existing UK Biobank participants who take part in the study will be asked to:

- complete some memory assessments and questionnaires.
- give a small amount of blood (25.5 ml; about 0.9 oz).
- have an MRI scan (pictures taken) of their brain.
- take a scratch-and-sniff smell test.
- wear a device home to measure heart rate, activity and sleep for 7 days.
- take a small sleep mat home (around 2 feet long and 7 inches wide) that will fit under their mattress and measure sleep patterns for 14 days.

The data collected in this study will be combined with other information and samples that our participants have already provided to UK Biobank.

By taking part, both you and your relative/friend could make a big difference to brain health research.

## **What will taking part mean for me?**

As a Study Partner, we would like you to accompany your relative/friend to the research centre. The visit will take approximately 3 hours. You will both be assisted around the centre by a member of UK Biobank staff who will provide help where needed.

The role of the Study Partner is outlined below:

- To provide a source of familiar support in the research centre that your relative/friend may need.
- To provide information/assistance during the MRI safety screening process, if your relative/friend needs it. This will involve answering questions about their medical history. If you are needed to support your relative/friend in the MRI room, we will need to check that you are safe to do so. Please also see the **MRI Information sheet**.
- With your relative/friend's consent, you will also be asked to answer some questions about their symptoms and daily living.
- In rare cases, you may be asked to help the participant express their wishes about taking part in the study to UK Biobank staff (this is called being a 'Personal Consultee').

## What is a Personal Consultee?

A 'Personal Consultee' is a person who is:

- engaged in caring for the participant (not professionally or for payment) or is interested in his/her welfare, and
- is prepared to be consulted.

The Personal Consultee advises the research team about what the participant's wishes and feelings would be if they were able to consent for themselves, and on whether they should take part. Further information is provided about this on page 7 of this information sheet.

## How will I get to the research centre?

We want to make it as easy as possible for you to take part. We can arrange door-to-door transport for you and your relative/friend, if that would be helpful. We will ask your relative/friend about this when we talk to them about the appointment.

If you prefer to use your own transport, we will provide you with directions and travel advice and will reimburse travel expenses. Please visit the Brain Health Study webpage for more information.

## Do I have to take part in the Brain Health Study?

No, you can choose whether to take part in the UK Biobank Brain Health Study. Having a Study Partner is optional, and it is likely that your relative/friend can still contribute to the study without a Study Partner if they wish. We understand that you may not have time or feel able to help.

You can change your mind about taking part at any point. Just let us know by calling our Participant Resource Centre on 0800 0 276 276 or emailing us at [ukbiobank@ukbiobank.ac.uk](mailto:ukbiobank@ukbiobank.ac.uk)

## Are there any benefits to taking part?

Whilst there are no immediate benefits for people taking part in the study, it is hoped that this work will enable researchers to:

- Define and identify different types of brain health conditions.
- Better understand the causes of these different types of brain conditions.
- Develop new treatments specific to each type of disease.

By taking part in the Brain Health Study, you will be helping to drive scientific discoveries that improve human health. Read more about UK Biobank's impact at <https://www.ukbiobank.ac.uk/learn-more-about-uk-biobank/our-impact>

## Are there any risks in taking part?

The Brain Health study visit should not cause you any harm. You will undergo a safety check to ensure any risks are minimised if you need to go into the MRI room to support your relative/friend. You have been sent an **MRI Pre-imaging Questionnaire** with this leaflet. To make sure it is safe for you to go into the MRI room, please fill out this form carefully. We have also sent you a copy of the **MRI Information sheet** sent to your relative/friend for your information.

## What happens to the information I provide to UK Biobank?

We will keep any identifiable information about you (for example your name and telephone number) safe and secure and will only use this data for administrative purposes. In addition, you may provide us with limited health data to enable us to check it is safe for you to enter the MRI scanning room to accompany a participant should you need to. This data won't be used for any other purpose.

Any data you provide to us which relates to your view / opinion of the symptoms and daily living of the participant for whom you are a Study Partner will be de-identified and stored in the UK Biobank resource alongside that participant's de-identified data. This de-identified data is then made available to bona fide researchers undertaking health related research that is in the public interest.

More detail can be found in our Brain Health Study Partner Privacy Notice available on our website at: <http://www.ukbiobank.ac.uk/brain-health-study-partner-policy>. A paper copy of this notice is available by calling our Participant Resource Centre on 0800 0 276 276, or from our Brain Health Study Research Centre(s).

## Further information for Consultees

When we are unsure about a patient's ability to make an informed decision to take part in research, we ask a relative or friend for their advice.

- To help decide if your friend/relative should join the Brain Health Study, we'd like to ask your opinion whether or not they would want to be involved. We'd ask you to consider what you know of their wishes and feelings, and to consider their interests.
- As a consultee, you will not give consent for your friend/relative, only advice.
- Please let us know of any advance decisions they may have made about participating in research. These should take precedence.
- If you decide your relative/friend would have no objection to taking part we will ask you to read and sign the Consultee Declaration form. We'll give you a copy to keep.
- If you are unsure about taking the role of consultee, you may seek independent advice. We understand if you do not want to take on this responsibility.
- The following information is the same as would have been provided to your relative/friend.

## Why has my friend/relative been invited to be in this study?

Your friend/relative is already one of half a million people who have given genetic, lifestyle and health information to UK Biobank.

They have been invited to take part in this Brain Health Study because they completed our Brain Health survey, and their answers show that they are eligible to take part.

## Does my friend/relative have to be in this study?

No, you can choose if your friend/relative should be in this study or not.

Your decision will not affect their ongoing relationship with UK Biobank.

You can change your mind about them taking part at any point. Just let us know. There is no need to give a reason.

## Is there anything that would mean my friend/relative would be unable to take part?

MRI scans use strong magnets so your friend/relative may not be able to have a scan if they:

- have an electrical implant (for example, a heart pacemaker or a shunt) in their body or,
- have had a brain implant like a clip or a coil.

Some medical problems may make it difficult for them to have a scan (for example, being unable to lie still on a flat surface for half an hour).

We will check if your friend/relative would be able to have a brain scan.

For more details, please see the **MRI Information sheet**.



## **Will my friend/relative find out the results from their visit?**

No, your friend/relative will not receive the results of the tests or a diagnosis. This is because the information we are collecting is just for research and is not checked by a doctor.

However, we will contact your friend/relative and their GP if the radiographer doing the brain scan sees something abnormal and unexpected that may be medically important.

In another UK Biobank study, we found abnormal appearances in 1 out of 100 brain scans. For half of these people, the abnormality turned out to be nothing to worry about.

Abnormalities might turn out to be something harmless like a cyst or a technical issue with the scan. It could also be related to a condition that your friend/relative and their GP already know about. However, other abnormalities might affect how their body functions, their quality of life, or their lifespan.

In case it is something more serious, we will ask for your permission to tell your friend/relative and their GP if we notice something in your scan.

Joining the study will not affect the care your friend/relative receives from their doctor.

## What will happen to my friend/relative's information?

The information we collect will be shared with approved researchers around the world for health-related research in the public interest. When we share your friend/relative's information, we remove their name and other personal information from their data and use codes instead. We do not include any details that will identify them in any information or samples we give to researchers. The data collected in this study will be combined with the other information and samples that they have already provided to UK Biobank. It will be stored securely by UK Biobank for many years. Your friend/relative's personal details e.g. (name, address, phone number, NHS number) are stored separately from any research data.

The way in which UK Biobank collects, shares, and uses your friend/relative's information is explained on our website at: [www.ukbiobank.ac.uk/explore-your-participation/basis-of-your-participation](http://www.ukbiobank.ac.uk/explore-your-participation/basis-of-your-participation). This includes an explanation of how we protect their data.

All researchers need to apply and get approval to use any UK Biobank data, and they must use it for health-related research that is in the public interest. This is the same for researchers from universities, charities, government agencies or commercial companies, and for researchers based in the UK or abroad.

Researchers must make public the results of all research using UK Biobank data so that everyone can benefit from it. You can find out about research that is being conducted using UK Biobank data on our website at:

<https://www.ukbiobank.ac.uk/learn-more-about-uk-biobank/our-impact>.

## What are the possible **BENEFITS** of my friend/relative taking part?

The study will not benefit your friend/relative directly. By taking part, they will help scientists better understand brain-related diseases and find new ways to prevent and treat these diseases for future generations.

## What are the possible **RISKS** of my friend/relative taking part?

The scan and other measures are safe, painless, and relatively quick and comfortable. Participating in this study should not cause your friend/relative any harm.

Your friend/relative may feel some discomfort when they have blood taken. There is the possibility of bruising and/or fainting, although our staff are trained to reduce the risk of this.

The MRI scan uses powerful magnets, and we take great care to prevent magnetic objects from entering the MRI room. When they book their appointment and when you arrive at the research centre, we will ask some questions about your friend/relative's medical history to check that it is safe for them to have a brain scan. We will also make sure that they are made as comfortable as possible during the scan. Please see the **MRI Information sheet** for more details.

Your friend/relative may find the research centre visit tiring, but they can take breaks when they need them. Our staff will be on hand to support them and help make their research centre visit as enjoyable as possible.

## Who has reviewed this study?

All 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 approved by the North West – Haydock Research Ethics Committee, ref. 21/NW/0157.

## What should I do if I have any questions?

If this information sheet does not answer your questions, please:

- visit our website at <https://www.ukbiobank.ac.uk/brain-health-study>
- phone us free of charge on 0800 0 276 276 (Monday to Friday 9am to 5pm); or
- email us at [ukbiobank@ukbiobank.ac.uk](mailto:ukbiobank@ukbiobank.ac.uk).

If you would like to contact the person in charge, please:

- send a letter to Professor Sir Rory Collins, Principal Investigator, UK Biobank, 1-2 Spectrum Way, Adswood, Stockport, Cheshire, SK3 0SA, or
- send an email to [ukbiobank@ukbiobank.ac.uk](mailto:ukbiobank@ukbiobank.ac.uk)

If you would like to make a complaint to a nominated person independent of the research team, please send an email to Nicola Perrin, MBE (Chair of the UK Biobank Ethics Advisory Committee) at [N.Perrin@amrc.org.uk](mailto:N.Perrin@amrc.org.uk)

We will reply to your letter or email promptly in writing, unless you ask us to phone you.

## Thank you for supporting UK Biobank.

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