



INFORMATION LEAFLET

Invitation to join a medical research study of the causes and prevention of disease in 500,000 people from around the UK

You are being invited to take part in a major medical research study called "UK Biobank". Before you decide whether to join, it is important for you to understand why the research is being done and what is involved. Please take the time to read the following information carefully, and discuss it with others if you wish.

If there is anything that is not clear, or if you would like more information, please telephone our Freephone number (0800 0 276 276) to talk to a member of the study team. More information about UK Biobank is also available at www.ukbiobank.ac.uk. At the study assessment visit, there would be a further opportunity to ask any questions about the study that you might have.

Thank you for taking the time to consider participation in this study.

Contact details:

UK Biobank
1-2 Spectrum Way
Adswold
Stockport
Cheshire
SK3 OSA

Freephone: 0800 0 276 276



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What is the purpose of UK Biobank?

UK Biobank is a medical research study that will show how the health of 500,000 people, currently aged 40-69, from all around the UK is affected by their lifestyle, environment and genes. The aim of this major study is to improve the prevention, diagnosis and treatment of cancer, heart disease, diabetes and a wide range of other serious illnesses.

By analysing the answers, measurements and samples collected from participants, medical researchers will be able to work out why some people develop particular diseases while others do not. This should help us to find new ways to prevent early death and disability from many different diseases.

Like giving blood for transfusions, UK Biobank may not directly help those who take part – but it should give future generations a much better chance of living their lives free of diseases that disable and kill.

How have I been chosen for invitation into UK Biobank?

People to invite are being identified from National Health Service (NHS) records. The only information provided to UK Biobank is your name, address, sex, date of birth, NHS number and general practice. This information is being processed by us in accordance with the Data Protection Act.

Your date of birth has allowed us to check that you are aged between 40 and 69 years. We have also been able to advise your general practice that their patients are being invited to take part.

We do not know anything else about you, and have not seen any of your medical records. Only if you attend the study assessment visit and give your written consent would we be able to access your medical records. (All such information would be held in strict confidence.)

What does taking part in UK Biobank involve?

Taking part in this medical research study would involve you in:

- Attending a local study assessment centre for about 90 minutes to answer some simple questions, to have some standard measurements, and to give small samples of blood and urine.
- Agreeing to allow your health to be followed for many years by UK Biobank directly through routine medical and other records.
- Being re-contacted by us to answer some additional questions and/or to attend a repeat assessment visit (which would be entirely optional).

What happens DURING the assessment visit?

The appointment at the assessment centre should only take about 90 minutes. During this visit, you would:

- Learn more about the study, and have the chance to ask any questions that you might have before deciding whether to join UK Biobank.
- Answer questions on your health, lifestyle, memory, work and family.
- Have measurements of blood pressure, pulse rate, height, weight, body fat, grip strength and lung function.
- Give small samples of blood (about 2 tablespoons) and urine for long-term storage and analysis (including genetic data).
- Receive some information about the key results of your examination, although the visit is not intended to be a “health check”. (None of your individual results will be released to your doctor or anyone else.)

N.B. If, for any reason, you might not be able to undergo some of the physical measurements described above then you can still take part in the study.

What happens AFTER the assessment visit?

For many years after the assessment visit, we would like to follow the health of everyone who agrees to take part, directly through their medical and other relevant records.

Some participants might be re-contacted by us and asked some more questions, although giving such additional help would be entirely optional. Similarly, some participants might be asked to attend a similar assessment visit in later years, although again attendance at such visits would be optional.

All of your information would be held in strict confidence with careful controls, and no identifiable information about participants would be available to anyone outside of the UK Biobank study.

What should I do if I want to take part?

If you would like to attend the local UK Biobank assessment centre to find out more about the study and possibly take part, then you will need to confirm your appointment.

You can do this most easily by **telephoning us (Mon-Sat; 8 am to 7 pm) free of charge on 0800 0 276 276**: if the appointment on your invitation letter is not convenient then you can change it easily during this call. Alternatively, you can let us know that the appointment on the letter is convenient by returning the completed form in the reply-paid envelope provided.

Please let us know if you have any special needs to help you get into the assessment centre (e.g. wheelchair access), or if you need any special assistance when you arrive (e.g. have poor vision or are hard of hearing).

What should I do if I do not want to take part?

If you definitely do not want to take part then we would be grateful if you would indicate this on the attached form and return it to us in the reply-paid envelope. Alternatively, you can telephone us on 0800 0 276 276. Letting us know that you will not be attending would allow us to give the appointment to someone else.

What can I do if I'm unsure about taking part?

More details about the study are given in the remainder of this information leaflet. If this does not answer all of your questions then please telephone us free of charge on 0800 0 276 276 (Mon-Sat; 8 am to 7 pm) and ask for more information. Alternatively, if you can access the internet (perhaps at home, work or in the local library), more details about the UK Biobank study and structure are available at www.ukbiobank.ac.uk

At the start of the assessment visit, there will be a further opportunity to ask any questions that you still have about the study. Attending for this assessment does not commit you to taking part.

Do I need to do anything BEFORE the assessment visit?

The main thing to do is confirm your attendance at the assessment centre for a day and time that is convenient for you. Then, it would be helpful if you could make a note on the questionnaire enclosed with your invitation about certain things that you might not otherwise remember during the visit:

- All medications, vitamins or supplements that you are taking regularly.
- All operations that you have had at any time in the past.
- Medical conditions that seem to run in your family.
- Your birthweight, whether breastfed, and place of birth (if known).

How do I prepare for the assessment visit?

When you attend your assessment appointment, please:

- Bring your completed pre-assessment questionnaire, and the directions for the assessment centre so that you don't have difficulties finding it.
- Bring any reading glasses that you might use as you will need to be able to read clearly.
- Wear light loose-fitting clothing and, if possible, avoid wearing tights or stockings as this will make some of the measurements easier.
- Be prepared to spend about 90 minutes in the assessment centre.

Do I have to take part in UK Biobank?

No; it is entirely up to you to decide whether or not to help with this study. If you do decide to take part you will be asked to sign a consent form during the assessment visit.

Why do you need my written consent?

Your participation in UK Biobank is entirely voluntary. By signing the consent form, you would be confirming your willingness to take part. In particular, you would be agreeing to:

- Answer some questions and have some measurements.
- Give blood and urine for storage and any testing (including genetic information in your DNA).
- Allow us long-term access to your medical and other records.
- Be contacted again in the future for this study.

Even if you do give your initial consent, you would be free to withdraw at any time later if you wished to do so. The study will be most valuable if few people withdraw, so please inform the assessment centre staff if you have any concerns with what taking part might involve.

Do I need to agree to everything?

No. If you feel uncomfortable about answering certain questions then you do not need to answer them. Similarly, if you do not want to have certain health measures, or to give a urine sample, then tell the staff.

We do, however, need your agreement to take a blood sample for storage and any tests (including genetic ones) that might be done for approved research. It will not be possible for you to give permission for some, but not other, types of research. We also need your permission to access your medical and other records in confidence for many years (even if you lose mental capacity or die). So, if you don't wish to agree to these parts of the study, you will not be able to join.

Are there any risks for me in joining UK Biobank?

No; taking part in UK Biobank should not cause you any harm. The study aims to observe what happens to participants over the next few decades so that future generations can benefit. It is not intended to change directly what happens to people who take part.

In particular, the initial assessment visit is not a "health check". Apart from providing you with the results of some standard measurements made during that visit, none of your results will be given to you or your doctors (even if the results do not seem to be normal).

It is possible that you may be slightly uncomfortable with some of the questions asked, or measurements made, during the assessment visit. Usually, you will be able to skip such questions or measures. You may also feel some discomfort when you have blood taken, although our staff are specially trained to help reduce any discomfort.

Over the coming years, a very wide range of tests will be done on your blood and urine samples for approved research. Details that might identify you will be removed from any information and samples provided to researchers, in order that they cannot be traced back to you. None of your particular test results will be fed back to you, your doctors or anyone else. So, taking part in the study should not have any adverse effects on you (including your employment status or ability to get insurance).

How will information about me be kept confidential?

UK Biobank has put a number of rigorous procedures in place to protect the confidentiality of participants. These include:

- Keeping information that might identify individuals (such as name and address) separate from other personal information in study databases.

- Computer security to block unauthorised access (for example, by “hackers”) to the study computers that hold personal information.
- Access to personal information is restricted within UK Biobank, and all staff sign confidentiality agreements as part of their contracts.
- Data or samples provided to researchers will not include any personal identifying details.

This should prevent identifiable information from being used – inadvertently or deliberately – for any purpose other than approved medical research.

Who will be able to use my information and samples?

Information and samples from UK Biobank participants will be available only to medical researchers who have relevant scientific and ethics approval for their planned research. This could include researchers who are working in other countries and in companies looking for new treatments.

Results from any tests made on participants or their samples will be put in the study database so that they are available to all approved researchers. There will also be a requirement to publish the results of all research that is based on UK Biobank so that people can benefit from it.

Insurance companies and employers will not be given any individual’s information, samples or test results. Nor will we allow access to the police, security services, relatives or lawyers unless forced to do so by the courts.

Results of research conducted on the UK Biobank resource will be made available to participants, and others who might be interested, through our website at www.ukbiobank.ac.uk

How do I withdraw if I want to do so?

After giving your signed consent, you can withdraw at any time during the assessment visit by telling one of the staff. You will be asked to confirm your withdrawal with a signature.

After the visit, you can withdraw by telephoning us on 0800 0 276 276 (Mon-Sat; 8 am to 7 pm) or by writing to the coordinating centre office. This would allow us to discuss your concerns with you.

If, having discussed the options and your concerns, you do decide to withdraw then we would send you a Withdrawal Form to confirm your wishes in writing. This form can be completed by you or, if you are not able to do so for some reason (such as illness), by someone able to act on your behalf.

Who is organising and funding UK Biobank?

UK Biobank has been set up by the government through the Department of Health, Medical Research Council and Scottish Executive, and by the Wellcome Trust medical charity. It is also supported by other charities, such as the British Heart Foundation and Cancer Research UK, as well as by the National Health Service.

UK Biobank is a non-profit charitable company set up to act as the legal owner and guardian of the database and sample collection. In signing the consent form, participants transfer all rights in their samples and data to UK Biobank (although they may withdraw at any time). The charity's role is to protect this valuable collection so that scientists can do a wide range of medical research in the future.

UK Biobank is a collaboration involving medical researchers from more than 20 UK Universities who have developed the study design. These plans have been reviewed by an independent group of international scientists and approved by the Northwest Multicentre Research Ethics Committee (MREC).

Who do I contact if I have any concerns?

If you have any concerns or complaints about anything to do with UK Biobank then you can telephone us on 0800 0 276 276 (Mon-Sat; 8 am to 7 pm) and ask to speak directly to one of the study organisers. Alternatively, if you would like to write to the person in charge, please send your letter to:

Professor Rory Collins
UK Biobank
1-2 Spectrum Way
Adswood
Stockport
Cheshire
SK3 OSA

We shall reply to your letter promptly in writing, unless you enclose your telephone number and wish to discuss your concerns with us.

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