



wellcome trust



INFORMATION LEAFLET

You are being invited to take part in a major medical research project called “UK Biobank”. The purpose of UK Biobank is to set up a resource that can support a diverse range of research intended to improve the prevention, diagnosis and treatment of illness, and the promotion of health throughout society.

Before you decide whether to join, it is important for you to understand why UK Biobank 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 anything is not clear, or if you would like more information, please telephone free of charge on 0800-0-276-276 to talk to a member of the project team. More information about UK Biobank is also available at www.ukbiobank.ac.uk. At the assessment visit, there will be a further opportunity to ask any questions that you might have.

Thank you for taking the time to consider taking part in UK Biobank.

Contact details:

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

Email: ukbiobank@ukbiobank.ac.uk

Freephone: 0800-0-276-276



What is the purpose of UK Biobank?

UK Biobank aims to study 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 purpose of this major project is to improve the prevention, diagnosis and treatment of a wide range of illnesses (such as cancer, heart disease, diabetes, dementia, and joint problems) and to promote health throughout society.

By analysing answers, measurements and samples collected from participants, researchers may 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 is not intended to help directly 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 identified from National Health Service (NHS) records. The only information used, in confidence, for this purpose is your name, address, sex, date of birth, NHS/CHI number and general practice. These details are processed centrally on behalf of the NHS 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 UK Biobank assessment visit and give your written consent would UK Biobank be able to access your medical records. (All such information would be held in strict confidence).

It is important that all types of people join UK Biobank. We would like you to take part whether you are in good health or have health problems, and whether you have a disability or may require help reading questions during the assessment visit. If you would welcome extra assistance to attend the assessment centre, or want to alert us to anything else beforehand, please telephone on 0800-0-276-276.

What does taking part in UK Biobank involve?

Taking part in UK Biobank would involve you in:

- Attending a local assessment centre for about 2 to 3 hours to answer some simple questions, to have some standard measurements and to give small samples of blood, saliva and urine.
- Agreeing to allow your health to be followed for many years by UK Biobank directly through routine medical and other health-related records.
- Being re-contacted by UK Biobank (e.g. to answer some more questions and/or to attend another assessment visit), although this would be entirely optional.
- Agreeing to have your samples and health-related information stored by UK Biobank and used in an anonymised form by researchers for many years.

What happens DURING the assessment visit?

The appointment at the assessment centre should take about 2 to 3 hours. During this visit, you would:

- Learn more about UK Biobank, and have the chance to ask any questions that you might have before deciding whether to join.
- Answer questions on your health, lifestyle and diet, memory, work and family history.
- Have non-invasive measurements of blood pressure, pulse rate, height, weight, body fat, vision, fitness, grip strength, bone density and lung function.
- Give small samples of blood (about 3 tablespoons) saliva and urine for long-term storage and analysis (including genetic data).
- Receive information about the key results of your measurements (see above), 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).

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

What happens AFTER the assessment visit?

For many years after the assessment visit, UK Biobank would follow the health of everyone who agrees to take part through their full medical records and other records that may be related to health (e.g. occupational or residential information).

Your blood, saliva and urine samples will not generally be analysed immediately following collection. Instead, during follow-up over the next few decades, your stored samples will be analysed for approved health-related research.

At some time in the future, participants might be re-contacted by UK Biobank and asked more questions, although giving such additional help would be entirely optional. Similarly, some participants might be asked in later years to attend another assessment visit (including questions, measurements and samples), although again attendance at such visits would be optional.

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

What should I do if I want to take part?

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

You can do this most easily by **telephoning us (Mon-Sat; 8.00am to 7.00pm) 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 completing and returning the reply-paid form provided with your invitation letter or visiting the study website at www.ukbiobank.ac.uk.

In most assessment centres appointments are available Monday to Friday from 8.00am to 7.00pm and Saturday from 8.00am to 5.00pm. 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 pre-paid reply form and return it to us. Alternatively, you can telephone us on 0800-0-276-276 or visit www.ukbiobank.ac.uk. Letting us know that you will not be attending will allow us to give someone else the appointment.

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

More details about UK Biobank 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; 8.00am to 7.00pm) and ask for more information. Alternatively, if you can access the internet (perhaps at home, work or in the local library), more details 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 participation. 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. We shall then send written confirmation of your booked appointment. In addition, a short pre-visit questionnaire will be included so that you can make a note about certain things that you might not otherwise remember:

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

Can I claim travel expenses?

Yes; you can claim back any reasonable travel expenses at the end of the visit by completing a simple claim form (it would be helpful if you kept any receipts). If you have any questions about travel expenses, please telephone us on 0800-0-276-276 (Mon-Sat; 8.00am to 7.00pm).

How do I prepare for the assessment visit?

When you attend your assessment appointment, please:

- Bring your completed pre-visit questionnaire, and the directions for the assessment centre so that you don't have difficulties finding it.
- Bring any reading glasses that you use as you will need to be able to read clearly from a computer screen (if you normally wear contact lenses it would be easier for the eye test if you could wear your glasses for the visit).
- Wear light loose-fitting clothing and, if possible, avoid wearing stockings or tights to make some of the measurements easier (e.g. those needing bare feet).
- Be prepared to spend about 2 to 3 hours 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 project. 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, saliva and urine for long-term storage and any testing (including obtaining genetic information and storing white blood cells so more DNA can be made).
- Allow UK Biobank to have long-term access to your existing and future medical and other health-related records.
- Be contacted again in the future by UK Biobank.

Even if you do consent to participate, you would be free to withdraw at any time later if you wished to do so (see below). The UK Biobank resource 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 or saliva sample, then tell the staff.

We do, however, need your agreement to take a blood sample, which will be stored and used for tests (including genetic ones) in 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 health-related 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 UK Biobank, you will not be able to join.

Are there any risks for me in joining UK Biobank?

Taking part in UK Biobank should not cause you any harm. The project 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).

This is because such feedback outside of the normal clinical setting is of questionable value, and might even be harmful (for example, causing undue alarm and having potentially adverse effects on insurance status), especially when given without prior counselling or support. For further details on this topic, please call 0800-0-276-276 or look on our website at www.ukbiobank.ac.uk.

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

Participation involves a minimal risk in relation to the use of personal information. Great care will be taken to ensure the confidentiality of all data (see below) and the risk to participants of a breach of confidentiality is considered very low.

Over the coming years, a very wide range of tests will be done on your blood, saliva and urine samples for approved medical and other health-related 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 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 in UK Biobank's databases from other information about participants.
- Computer security to block unauthorised access (for example, by "hackers") to the computers that hold personal information.
- Access to personal information is restricted within UK Biobank, and all staff sign confidentiality agreements as part of their employment contracts.
- Data or samples provided to researchers will not include personal identifying details.

This should prevent identifiable information from being used – inadvertently or deliberately – for any purpose other than to support the project.

Who will be able to use my information and samples?

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

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

Insurance companies and employers will not be given any individual's information, samples or test results, and 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 anyone else who might be interested, at www.ukbiobank.ac.uk.

How do I withdraw if I want to do so?

UK Biobank will be most valuable if few people do withdraw from it, so potential participants are asked to discuss any concerns that they might have with a member of the project team before agreeing to participate.

During the assessment visit, you can withdraw at any time after giving your signed consent, 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; 8.00am to 7.00pm) or by writing to the coordinating centre office. This would allow us to discuss your concerns with you and to determine the desired level of withdrawal from the following options:

- *"No further contact"*: This means that UK Biobank would no longer contact you directly, but would still have your permission to retain and use information and samples provided previously and to obtain and use further information from your health records.
- *"No further access"*: This means that UK Biobank would no longer contact you or obtain further information from your health records in the future, but would still have your permission to use the information and samples provided previously.
- *"No further use"*: This means that, in addition to no longer contacting you or obtaining further information about you, any information and samples collected previously would no longer be available to researchers. UK Biobank would destroy your samples (although it may not be possible to trace all distributed sample remnants) and would only hold your information for archival audit purposes. Your signed consent and withdrawal would be kept as a record of your wishes. Such a withdrawal would prevent information about you from contributing to further analyses, but it would not be possible to remove your data from analyses that had already been done.

If, having discussed the options and your concerns, you did 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 Department of Health, Medical Research Council and Scottish Government, and by the Wellcome Trust medical charity. It is also supported by the Welsh Assembly Government, by health research charities (such as the British Heart Foundation, Cancer Research UK and Arthritis Research Campaign) and by the National Health Service.

UK Biobank is a not-for-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 property and intellectual property rights in their samples and data to UK Biobank. The charity's role is to protect this valuable resource so that scientists can do a wide range of health-related research in the future.

UK Biobank collaborates with scientists from more than 20 British Universities who have developed its design. These plans have been reviewed by an independent group of international scientists and approved by the NHS North West Research Ethics Committee. In addition, the independent Ethics and Governance Council will monitor the development and use of the resource (for more information, see www.egcukbiobank.org.uk).

What happens if something goes wrong?

The risks of participants suffering harm as a result of taking part are minimal, and UK Biobank has insurance in place to provide compensation for any negligent harm caused by participation.

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 free of charge on 0800-0-276-276 (Mon-Sat; 8.00am to 7.00pm) and ask to speak directly to one of the 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
Adswold
Stockport
Cheshire
SK3 0SA

Email: ukbiobank@ukbiobank.ac.uk

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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