



FURTHER INFORMATION LEAFLET

(supplementing the main Information Leaflet)

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.

If anything is not clear, or more information is required, 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.

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Who is involved in UK Biobank?

UK Biobank has been set up, and is funded, 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, health research charities (such as the British Heart Foundation, Cancer Research UK and Arthritis Research Campaign) and the National Health Service.

This major medical research project is being run as a not-for-profit charity with initial funding of about £62 million. The Chair of its Board of Directors is Sir Alan Langlands, who was previously Chief Executive of the NHS. Details of Board members are given on our website at www.ukbiobank.ac.uk.

UK Biobank has its headquarters at Manchester University. The Principal Investigator and Chief Executive is Professor Rory Collins, who is also British Heart Foundation Professor of Medicine & Epidemiology at Oxford University. Other senior members of the team in Manchester are the Executive Director, Dr Tim Peakman, and the Chief Scientific Officer, Dr Tim Sprosen.

This national project involves more than 20 collaborating British universities grouped into six teams (with several other universities also contributing to its success in different ways):

Central England: Oxford University.

Fosse Way: Birmingham, Leicester, Nottingham, Sheffield, Warwick, Exeter and Plymouth Universities.

London: Imperial College, University College, Kings College and Queen Mary University of London.

Northwest/Wessex: Manchester, Keele and Southampton Universities.

Scottish: Aberdeen, Dundee, Edinburgh and Glasgow Universities, and the Information and Statistics Department of NHS Scotland.

Welsh: University of Wales at Bangor, Cardiff and Swansea.

The UK Biobank Steering Committee represents the investigators at these universities, and is responsible for the project's scientific design and conduct. Professor Collins is the Chair, and the other members are Professors Valerie Beral, Paul Burton, Paul Elliott, Alan Silman, Jill Pell and John Gallacher.

The Steering Committee, Board and funders receive independent scientific guidance from an International Scientific Advisory Board. UK Biobank's research activities are also reviewed and approved by the North West Research Ethics Committee. Further guidance and monitoring is provided by an independent Ethics & Governance Council (www.egcukbiobank.org.uk) chaired by Professor Graeme Laurie, Professor of Medical Jurisprudence at Edinburgh University.

What does UK Biobank involve?

UK Biobank is a major medical research project on the impact on health of lifestyle, environment and genes in 500,000 people currently aged 40-69 from all around the UK. This age group is being studied because it involves people at risk of developing serious diseases – including cancer, heart disease, stroke, diabetes, dementia – over the next few decades.

The National Health Service treats the single largest group of people anywhere in the world, and keeps detailed records on all of them from birth to death. Consequently, follow-up of UK Biobank participants through routine medical and other health-related records will allow identification of those who develop a wide range of disabling and life-threatening conditions. This will make UK Biobank a uniquely valuable resource for medical and other health-related research.

Scientists have known for many years that our risks of developing different diseases are due to the complex combination of different factors: our lifestyle and environment (exposures); our personal susceptibility (genes); and the play of chance (luck). Because UK Biobank will involve thousands of people who develop any particular disease, it should be able to show more reliably than ever before why some people develop that disease while others do not. This should help to find new ways to prevent death and disability from many different conditions.

People to invite into UK Biobank are identified from NHS records. The only information used, in confidence, for this purpose is name, address, sex, date of birth, NHS/CHI number and general practice (with no medical information). These details are processed centrally on behalf of the NHS, in accordance with the Data Protection Act, to generate invitation letters. General practitioners are advised that people registered with their practices may be invited to take part.

Taking part in UK Biobank involves participants in:

- Attending a local assessment centre for about 2 hours to answer some simple questions, to have some standard measurements, and to give small samples of blood (about 3 tablespoons) saliva and urine.
- Agreeing to allow their health to be followed for many years by UK Biobank directly through routine medical and other health-related records (e.g. occupational health).
- Being re-contacted by UK Biobank at some time in the future to answer more questions and/or attend another assessment visit (including questions, measurements and samples) although giving such extra help would be entirely optional.
- Agreeing to have their samples and health information stored and used, in confidence, by approved researchers for many years.

A very wide range of tests will be done on the blood, saliva and urine samples for approved medical and other health-related research, and it is impossible to predict all of the uses to which the samples might be put during the next few decades. But, since none of these individual test results will be fed back to participants, their doctors or anyone else, taking part in UK Biobank should not have any adverse effects on participants (including their employment status or ability to get insurance).

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. Taking part in UK Biobank is not intended to help participants directly, but it should give future generations a much better chance of living their lives free of diseases that disable and kill.

What happens to the blood, saliva and urine samples?

Small samples of blood, saliva and urine are collected from each participant during the assessment visit. The staff put them into several different tubes which allow a wide range of different measurements to be made. Some of the tubes are then spun in the assessment centre to allow immediate separation of the blood into its constituent parts (red cells, white cells, plasma or serum).

At the end of each day, the samples are transported overnight to the UK Biobank laboratory in Manchester for further processing and storage. Each sample is separated into several smaller tubes for frozen storage. Processing also includes preserving the white blood cells in such a way that they can be grown and more genetic material produced in the future. As the laboratory may receive up to 1000 samples each day, this process is highly automated and samples are bar-coded (as in a supermarket) so that computers can keep track of them.

By the end of recruitment, UK Biobank will be storing about 15 million individual tubes of blood, saliva and urine. Samples from each participant are stored in two separate locations in order to protect this precious resource against loss. One location holds the “working” store that will be used first for any approved research studies, and the other location holds the “back-up” store that will be used when samples in the working store have been used up.

The working store is a huge purpose-built -80°C freezer room that uses computer-controlled robots to put away and retrieve the samples. This allows UK Biobank to keep careful track of the location of each participant’s samples, and to retrieve those that are needed for particular studies rapidly and accurately. It will be the first such automated store anywhere in the world, and has been developed jointly with specialist British companies.

The back-up store holds the reserve samples from participants in several dozen liquid nitrogen tanks at about -200°C . This very low temperature ensures that even very unstable things in the blood can be measured many decades later. The back-up store does not use robots because these samples do not need frequent retrieval. But it still uses computers to keep track of each participant’s samples, and automated systems to control the temperature.

The UK Biobank resource will become increasingly valuable for medical and other health-related research over the years, so it is likely that these samples will be kept for several decades. However, if and when it is thought that the resource has reached the end of its natural life, then all of the samples will be destroyed.

How is the confidentiality of participants protected?

Confidentiality of participants' data is a top priority for UK Biobank. Stringent security measures to prevent unauthorised use are in place, including: access control, computer security, confidentiality agreements and staff training.

Information that is likely to identify participants (such as name, address, date of birth) is removed from their other study data and samples as soon as possible after collection. All data are stored anonymously in UK Biobank's database, with personal identifiers kept separately under strict control with restricted access.

It is necessary to be able to link participants' identifiers with their personal data (including any test results) in order to be able to add information obtained subsequently from medical records or other sources during follow-up. This is done using a carefully controlled code, which can be accessed by only a limited number of UK Biobank staff solely for the purposes of such linkage.

Computer security systems are in place to block unauthorised access (for example, by "hackers") to the study computers that hold personal information. In particular, UK Biobank's computers are protected against direct contact from other computers and the internet by special "firewall" software (as used in commercial banks). Also, the level of access that is allowed to staff within UK Biobank is controlled by unique user names and passwords, and restricted on the basis of their need to carry out particular duties.

Data or samples provided to researchers outside UK Biobank will not include any personal identifiers. Moreover, such researchers must confirm that they will not make any attempt to identify individual participants or to contact them directly. UK Biobank staff also sign confidentiality agreements as part of their job contracts, and are trained in the appropriate handling of personal data.

Who will be able to use UK Biobank information and samples?

UK Biobank is the legal owner of the study data and sample collection. It will serve as the “steward” of this precious resource, maintaining and building it for the public good in accordance with its access policy, which is available at www.ukbiobank.ac.uk. In signing the consent form, participants transfer all property and intellectual property rights in their samples to UK Biobank.

Information and samples from UK Biobank participants will be available only to researchers who have relevant scientific and ethics approval for their planned research. No one will be given exclusive or preferential access to the UK Biobank resource. Results from any tests made on participants or their samples will be put in the study database so that they are available to all other approved researchers. There will also be a requirement to publish the results of all research based on UK Biobank so that people can benefit from it.

Pharmaceutical and other health-based companies will be able to access the study data for approved research, as this may help in the identification of new treatments. All users, whether employed by universities, government, charities or commercial companies, will have access only to anonymised information and will be held to the same scientific and ethical standards.

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. Access will only be granted voluntarily under strict controls to researchers whose studies have been approved by UK Biobank.

Participation in UK Biobank is entirely voluntary. After giving signed consent, participants can withdraw at any time (see below). The level of withdrawal may range from “No further contact” (but allowing continued use of information and samples, and further information to be obtained from records) to “No further use” (requiring destruction of all of the participant’s information and samples).

The interests of participants and the public are at the heart of UK Biobank. An Ethics and Governance Framework has been written to help make sure that participants are protected, and that the resource is used only for scientifically and ethically approved research (this document is available at www.ukbiobank.ac.uk). The independent Ethics & Governance Committee will monitor the conduct of UK Biobank and the development and use of the resource (for more information, see: www.egcukbiobank.org.uk).

How do participants withdraw if they 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.

After giving their signed consent, however, participants can withdraw at any time either by telephoning 0800-0-276-276 (Mon-Sat; 8.00am to 7.00pm) or by writing to the coordinating centre office. This will allow particular concerns to be discussed and the desired level of withdrawal to be determined:

- “No further contact”: This means that UK Biobank would no longer contact the participant directly, but would still have their permission to retain and use information and samples provided previously and to obtain and use further information from their records.
- “No further access”: This means that UK Biobank would no longer contact the participant or obtain further information from their records in the future, but would still have their permission to use the information and samples provided previously.

- “No further use”: This means that, in addition to no longer contacting the participant or obtaining further information about them, any information and samples collected previously would no longer be available to researchers. UK Biobank would destroy their samples (although it may not be possible to trace all distributed sample remnants) and would only hold their information for archival audit purposes. Participant’s signed consent and withdrawal would be kept as a record of their wishes. Such a withdrawal would prevent information about them from contributing to further analyses, but it would not be possible to remove their data from analyses that had already been done.

If, having discussed their concerns and options, a participant decides to withdraw then UK Biobank would seek written confirmation of this decision from the participant or someone able to act on their behalf.

What are the values on which UK Biobank is based?

UK Biobank is a “public good” resource, and we are committed to respecting the human rights of participants. Most particularly, UK Biobank has an ethical and legal commitment to respecting the confidentiality and privacy of information about participants and to managing that information in compliance with the principles of data protection. This means that all information will be stored and processed securely, and used only for lawful purposes.

Who to contact about any questions or concerns?

Anyone who has any questions about UK Biobank can telephone us free of charge on 0800-0-276-276 (Mon-Sat; 8.00am to 7.00pm) to ask for more information. Alternatively, those with access to the internet (perhaps at home, work or in the local library) can get more details from www.ukbiobank.ac.uk.

For any concerns or complaints about anything to do with the project then please telephone us on 0800-0-276-276, and ask to speak directly to one of the study organisers. Alternatively, write to the person in charge:

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