

Imperial Health Knowledge Bank

Information for participants version 3.0 19/09/2023

Introduction

We would like to invite you to take part in Imperial Health Knowledge Bank run by Imperial College Healthcare NHS Trust in collaboration with Imperial College London. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. If there is anything that is not clear or if you would like more information, you can contact us via email imperial.healthknowledgebank@nhs.net or you can visit www.imperial.nhs.uk/knowledgebank.

This leaflet can be provided on request in large print, easy read version, as a sound recording, in Braille, or in alternative languages. Please contact the communications team on 020 3312 5592.

What is Imperial Health Knowledge Bank?

Imperial Health Knowledge Bank aims to build a database of individuals, with and without health conditions, who are interested in taking part in future health research studies and who allow us to store biological samples for research and teaching medical professionals about health conditions. It brings together our patients, clinicians and researchers to increase understanding of health conditions, detect diseases earlier, develop new tests and treatments and improve clinical training. We have called it a Bank because it contains very valuable information that could improve the health of our community.

Do I have to join Imperial Health Knowledge Bank?

No. It is completely up to you to decide whether or not you wish to join. If you decide not to join, it will not affect the standard of care that you receive in any way. If you do decide to join, you will be free to withdraw at any time and without having to give a reason. A

decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What would taking part in Imperial Health Knowledge Bank involve?

After providing your consent to take part, there are three things we will do.

1. Add your details into Consent to Contact database

We will add you to our database of people who are interested in taking part in future health research. The reason we do this is that we want to give you the option to take part in further research studies that are relevant to you. To do this we need to be able to contact you to provide further details of these studies so you can decide if you want to take part. This means we may contact you in the future to give you details about a specific study and ask for your permission to share your contact details with the researcher running it. You have the right to say no. Your identity will never be shared without your permission.

When and how will I be contacted about research studies?

If your pseudonymised health data matches the requirements for a research study that may be relevant to you, an NHS approved staff member will contact you and provide you with more information. If you are interested in taking part in that research study, with your permission your contact details will be passed on to the study researchers who will get in touch with you.

You decide if you want to take part. It is your choice and you do not have to take part in any studies if you do not wish to. If you decide not to take part, it will not affect the standard of care that you receive in any way.

We will also share your contact details with the North West London-wide NHS research register, Discover. All of the same conditions apply for involvement in Discover. You can find out more about Discover at <https://www.registerfordiscover.org.uk/about-discover/overview>

What is pseudonymised data?

Your information will be pseudonymised, pseudonymisation refers to technique that replaces, removes or transforms information that identifies an individual, for example replacing a name with a reference number. Your identity will never be shared without your permission.

2. Use your clinical data for research

We will collect, store and analyse health information about you, including accessing your medical records. Researchers will use this information to do research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead to ensure this information will not identify you.

We will keep all information about you safe and secure.

3. Collect blood samples for research

You will be asked to provide 2 blood samples the next time you attend hospital for your usual appointments. We will take up to 10 millilitres (ml) - two teaspoons - of blood to be

kept for research. You will not need to make any extra visits to the hospital - we will only take this extra blood either the same day you agree to join the Imperial Health Knowledge Bank or when you come to a clinical appointment at one of our hospitals. We will store these two blood samples for use in future research projects.

Will the samples be tested for (genetic) inherited disorders?

We want to know how genes influence health and disease. Genes are made up of DNA (deoxyribonucleic acid). We may, now or in the future, isolate, analyse and store a sample of your DNA from your donated blood sample and study your genetic makeup. We may also test other components of your blood, such as cells, RNA, protein and metabolites. Your samples will be kept in a secure location.

This part is optional. If you do not wish to provide blood samples or want your blood to be genetically tested through DNA analysis, you do not have to consent to this part. You can still take part in the consent to contact database part of IHKB.

Who will use the stored samples?

Your sample may be used by researchers based in academic institutions e.g. universities, the NHS or commercial companies such as pharmaceutical companies. All of your information will be coded, which means we will remove your name from the blood samples and replace it with a code number. The samples will not contain details that could directly identify you.

Will my details be kept confidential?

Yes. Best ethical and legal practices will be followed to ensure that all information collected about you will be handled safely and securely. Your personal details will never be released to researchers without your consent.

Your samples will be labelled with a unique number before being transferred to the laboratory for testing. Data about you (e.g. personal details and health information) will be stored in secure electronic databases. Any information from genetic and other tests or analyses will be stored separately from your personal details. Access to your personal details will only be available to authorised members of the IHKB (for example, to invite you to take part in other research studies). Your samples can only be accessed by researchers once they have been coded with all identifying information removed.

Researchers can apply to access your samples or data, and they have to explain how they will use it, e.g. the research question they wish to answer. Any researcher, who wants to use your samples or data for their research will need to submit an application to a special committee set up by the Trust involving clinicians, academics and patient representatives before being allowed access to your samples and pseudonymised data. This committee will ensure that the research is scientifically valid, in the interests of human health and has appropriate security measures to protect your information. Your samples and data will be shared in a non-profit way. This means we will not sell or make a profit from the samples shared with researchers.

Can I know the results obtained from my study samples?

The IHKB does not provide a report or feedback on any genetic or laboratory results obtained from your sample, as it is taken for research purposes only.

Will any of the results obtained with my sample predict the risk of disease?

We cannot answer this question. Many of the studies that the IHKB supports aim to discover variations in the genetic code ('genetic markers') that might predict the risk of certain diseases. However, it may be years before researchers can confirm how important or accurate these markers are and determine the associated risk.

If you are contacted to take part in a future study, this does not mean that your health is at risk. Genetic variation between individuals can both protect and put individuals at risk of disease. We are a long way from understanding how they balance each other and what combination of markers combined with other factors such as age, gender, smoking and drinking habits, increases the risk of disease.

Some of the studies the IHKB may invite you to take part in could reveal unexpected/previously unknown health conditions or future health risks. You will have the opportunity to confirm if you are happy to be invited to these studies at the time.

What happens if an invention is made using my sample?

Your donated samples and related information are given as a gift, which may help researchers in the public and commercial sector make an invention that could improve the future healthcare of patients and blood/organ donors, such as a new product to diagnose or treat a condition. If an invention results from the research undertaken with your sample and/or information, you will not receive any compensation, recognition or payment. The IHKB will not share your sample to make a profit. Published studies are available to view on the NIHR IHKB website <https://imperialbrc.nihr.ac.uk/facilities/ihkb/>

How will I benefit from joining Imperial Health Knowledge Bank?

You may not benefit personally from any research carried out using your samples and data. However, the use of your samples and data may lead to the development of new drugs, treatments or tests and the results of the research may benefit patients in the future. You will not receive a financial reward now or in the future for providing samples. The clinical team involved in your treatment and care will receive no payment because of your involvement in IHKB.

What will happen to the results of the study?

Research studies usually take several years to complete. The results from these studies will be used to improve treatment and care of patients in the future. Results will be reported in scientific publications and we will share regular updates of research in progress, research results and other relevant information through our website and a dedicated e-newsletter. You will not be identified in any publication or through any information on the website.

What if something goes wrong?

Imperial College Healthcare NHS Trust holds standard NHS Hospital Indemnity and insurance cover, which apply to this study. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the IHKB team imperial.healthknowledgebank@nhs.net

The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial Research Governance and Integrity Team RGIT@imperial.ac.uk

How will we use information about you?

We have a legal duty under the Data Protection Act 2018 to keep your information confidential, secure and hold the data only as long as necessary. The Trust collects and stores data about you in order to provide safe and effective healthcare. Your health records are held on paper and on secure computer systems. The Trust allows pseudonymised data from health records to be used to conduct ethically approved research and this health data may be linked to blood samples you provide. This allows research to occur without impacting patients' privacy. Your full, identifiable health record will never be seen by researchers without your explicit consent.

Everyone involved in this study will keep the data collated as part of this study, including your personal data, safe and secure. We will also follow all privacy laws and legislation that are relevant to the specifics of the study.

We will need to use information from your medical records for this research project. This information will include your

- Full name;
- NHS number;
- Date of birth;
- Contact details, including address, phone number and email address;
- Name and contact details of your GP;
- Health-related information, e.g., on your lifestyle, disease history, medication etc.;
- Genetic information that will be generated from your blood samples

People will use this information to do the research or to check your records. People who do not need to know who you are will not be able to see your name or contact details.

Information about you, but not your personal identifiable information, may be shared with researchers in other countries worldwide. They must follow our rules about keeping your information safe.

Only NHS approved staff will use your contact details to tell you about research studies that may be relevant to you based on your health information. You do not have to take part in any studies if you do not wish to.

You have a right to a copy of the information that we hold about you. To request this information please write to the subject access requests team via the details listed at the end of this leaflet. For more information about your rights please refer to the Trust-wide patient privacy notice at <https://www.imperial.nhs.uk/privacy>

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep all information about you safe and secure.

I would like to join Imperial Health Knowledge Bank – what should I do next?

If you would like more information: email us via imperial.healthknowledgebank@nhs.net or go to <https://imperialbrc.nihr.ac.uk/facilities/ihkb/>

I no longer want to be a member of Imperial Health Knowledge Bank – what do I need to do?

You can leave Imperial Health Knowledge Bank at any time without giving a reason and without your care or legal rights being affected.

If you want to leave Imperial Health Knowledge Bank, please contact the team via email imperial.healthknowledgebank@nhs.net

If you choose to withdraw, you have two options.

1. You can allow us to continue accessing your healthcare records from central NHS records and/or research done with your sample. This is a 'no further contact' withdrawal.
2. You can ask us to stop further use of your data and to destroy your remaining samples. Any research that has used your data or sample(s) cannot be undone. This is 'no further use' withdrawal.

Your personal information will be retained in an archive so that a record remains of your initial consent and the withdrawal process. If the IHKB is unable to confirm your decision, your sample(s) and data will be retained for future use, and you will not be contacted again.

Who has approved/reviewed the collection of human tissue samples as part of Imperial Health Knowledge Bank?

The research ethics committee that has approved – and will regularly review the Imperial Health Knowledge Bank is London-Fulham Research Ethics Committee.

Contact details for the data protection officer

Philip Robinson
Data Protection Officer
ICT Directorate
St Mary's Hospital
London
W2 1NY
Email: imperial.dpo@nhs.net
Phone: 020 370 48356

Enquiries relating to Subject Access Requests (DPA) should be sent to – imperial.accesstohealthrecords@nhs.net

Imperial College Healthcare NHS Trust is a registered data controller under the Information Commissioner's Office. Further information can be found at:
Information Commissioners Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

Website: www.ico.org.uk/concerns
Phone: 0303 123 1113

If you are not satisfied with our response or believe we are processing your personal data not in accordance with the law you can complain to the Information Commissioner's Office.

Contact details for Imperial College Healthcare's patient advice and liaison service (PALS)

If you have any questions or comments about your care, please contact PALS on **020 3313 0088** (Charing Cross, Hammersmith and Queen Charlotte's & Chelsea hospitals), or **020 3312 7777** (St Mary's and Western Eye hospitals). You can also email PALS at pals@imperial.nhs.uk The PALS team will listen to your concerns, suggestions or queries and is often able to help solve problems on your behalf.