Heart, Lung and Critical Care (HLCC) Biobank

Adult - Information for Patients, Family Members & Healthy Volunteers on Donating Samples and Healthcare Information.

Introduction

This leaflet gives information on the Heart, Lung and Critical Care (HLCC) Biobank, at Royal Brompton and Harefield Hospitals, part of Guy's and St Thomas' NHS Foundation Trust. It explains the purpose of the Biobank, what it involves for you, and what your samples and healthcare information may be used for. Please read it carefully and feel free to ask for further information.

What is the Heart, Lung and Critical Care (HLCC) Biobank?

Guy's and St Thomas' NHS Foundation Trust has a well-established Biobank for the storage of tissue, blood and other bodily fluids from patients with heart and lung diseases, family members and healthy volunteers. The purpose of the Biobank is to allow research into heart and lung diseases. The Biobank is very valuable because it will help support to find new ways of identifying, treating and preventing diseases in these areas.

Why have you been asked to take part?

You are being invited to donate samples and healthcare information because you are a patient, a family member of someone with a heart or lung condition or a healthy volunteer.

Do you have to take part?

No. You are free to say no if you don't want to take part – the choice is yours. Your decision will NOT affect the standard or type of treatment you will receive from the hospital or doctors, now or in the future. If you say no, we will not collect any research samples and we will not collect any information. Taking part is completely voluntary.

What are we asking you to do?

We are asking permission to collect and store samples which are **surplus** (left over) to diagnosis and/or to donate **additional** (extra) samples to the Biobank. These are explained in further detail below.

1. **Surplus Samples:** When you have a medical procedure, such as surgery or a diagnostic test, samples such as tissue or fluid may be collected to help diagnose and treat your condition. In some cases, not all of these samples are required for your care, and we would like to keep these surplus samples for the Biobank, which would otherwise be disposed of.

For transplant patients, these surplus sample(s) may include your diseased heart or lungs once it has been removed during your transplantation procedure.

2. **Additional Samples:** In addition to surplus samples, we may ask for your permission to

collect extra samples specifically for research. These additional samples are entirely optional and will only be collected during your routine treatment or follow-up care if appropriate. These might include blood, urine, saliva, or other types of samples listed in the table.

You will not be asked to donate all these samples. The types of sample(s) you will be asked to donate will depend on the procedure you are having as part of your clinical investigations.

For example, you will only be asked to donate an extra tissue (biopsy) sample if you are having a bronchoscopy and it is part of your necessary clinical investigation/care, which will allow for the collection of the sample.

For any additional samples that will be taken, the amount of sample that is taken will be decided by your doctor with your best interests in mind and is safe to do so. Specific details about this sample collection will be noted in your medical record.

Occasionally, we may also ask family members including non-patient healthy volunteers (including professional colleagues, friends and carers) who do not have an illness to provide blood, saliva or stool samples. This is important because it can provide a baseline for comparison with patient samples, helping researchers identify differences and better understand how diseases develop and progress.

Details of additional samples are given in the table below and can be explained to you by a member of your clinical care team in further detail. All the procedures are well established and used on a routine basis at Guy's and St Thomas' NHS Foundation Trust.

Sample	Details	Risks
Blood	You might be asked to donate approximately 4 tablespoons (60ml) of blood from your arm. Blood can sometimes be taken whilst you are having blood taken for clinical investigation.	There is a risk of a small bruise from blood sampling and a small risk of fainting in a small number of patients.
Urine	You might be asked to pass urine into a sample pot	There are no associated risks.
Saliva	You might be asked to provide a saliva sample by spitting into a sample pot.	There are no associated risks.
Sputum	You might be asked to cough up sputum (phlegm) from deep inside your lungs. Sputum from your lungs is usually thick and sticky whereas saliva comes from your mouth and is watery and thin.	There are no associated risks.
Tissue	You might be asked to donate a small tissue sample when you are having a planned biopsy or surgical procedure.	Risks include pain, infection, and bleeding.

Lavage	You might be asked to donate a sample of liquid collected from your lungs.	Risks include pain, infection, and bleeding.
Brushings	You might be asked to donate a sample collected from the surface of your nose or lungs using a small brush.	Risk of slight bleeding or irritation at the collection site.
Swabs	You may be asked to provide nasal or throat swabs.	Risk of slight bleeding or irritation at the collection site.
Stool	You might be asked to provide a stool sample using a sample pot.	There is a minimal risk of cross infection, however thorough hand washing will significantly reduce this risk.

What will happen if you say yes?

If after reading this information leaflet and you agree to take part, you will need to give your permission (consent) by signing a Biobank consent form which we will provide. You may be approached for consent when you attend your clinic appointments at the hospital where the doctor, research nurse or Biobank staff will answer any questions you have and show you how to complete the form and where to sign. You may also receive a telephone call for remote consent after your clinical consultation, where you will be given information about the Biobank and guided through the form and offered various options to review and sign, including:

1. Receiving a copy of the consent form via email to sign electronically, or print at home, sign, and email back.
2. Receiving a printed copy of the consent form through the post to sign and return in a prepaid envelope provided.
3. Signing the form during your next hospital appointment.

We will confirm receipt of your signed consent form and will return a completed copy back to you. This will also be added to your medical records.

If you agree to take part:

- Samples collected from you will be processed in a variety of ways and labelled with a specialised number and barcode (not your name or address) and stored in a secure freezer.

- After a period of time the coded sample(s) you have provided may be passed on to our researchers for use in one or more approved research studies. Research studies will be first assessed and approved by a committee composed of doctors, scientists, and patient advocates before being provided to researchers.

- The Biobank would benefit for the purposes of research from following up your medical health status over your lifetime (even after your incapacity or death) at periodic intervals. Therefore, we may wish to contact your GP/hospital or other national registries which store information about your NHS treatment which is managed by NHS Digital. The Trust will adhere to all data protection laws (Data protection Act 2018 and UK GDPR) and regulations when collecting, storing and processing your information.

- As part of your standard healthcare, you may have had tests or samples taken at other healthcare organisations. These samples and data might have been kept as part of your medical record and could be valuable for research when linked to your HLCC Biobank donations. We would like your permission to contact the hospital Trusts where you've received treatment to request these samples or data for use in approved studies.

- It is possible that we may share some of your coded sample(s) and healthcare information with researchers in other hospitals, academic laboratories or commercial organisations (such as a company manufacturing a drug) within the UK and abroad. Any sample(s) and health data shared in this way will remain coded and will not be labelled with personal information such as your name or address.

- Your samples may be used to study signs of illness to improve how we monitor conditions, see how treatments are working, and learn more about what happens in unhealthy cells compared to healthy ones. Researchers may want to look at your genetic material, such as your DNA or RNA, to better understand your unique biological makeup. This information helps them develop better ways to diagnose and treat diseases in the future.

- In future appointments we may ask you if you are still happy to donate further samples to help us with our research. This would be no more than three times a year. These samples will be managed in exactly the same way as the original samples that you donated. If you choose not to have these it will not affect your care. The reason we may ask for further samples is that for some research studies it is beneficial to have samples from the same person at different time points. For example, the levels of substances in your blood known as biomarkers can change over time, it can be helpful to researchers to study these over a number of years.

- It is hoped the outcomes of your treatment will be valuable to research. We may from time to time approach you to complete some questionnaires about your health, well-being, and quality of life. We will ensure these are not frequent and they would not exceed more than 25 minutes at a time. You do not have to respond to any of these questionnaires as they are optional. The questionnaires could be posted back to us in a pre-paid envelope. Alternatively, if you would prefer, the questionnaires may be completed electronically or over the phone at a time that is convenient to you.

- Your donated samples will be stored for a period of up to 10 years. If there are any unused samples after this time, a decision will be made by the Biobank Committee at the hospital

either to keep the remaining samples or dispose of them in line with the standard hospital disposal procedures for human samples.

- Your doctor, research nurse or Biobank staff may ask you some questions. This may include details such as your age, height, weight, smoking history and medical condition. We also ask if they can have permission to look at your medical records to obtain information about your health, any tests you may have had, any other diseases which you or your relatives may have, and your past treatment. Data collected about you will be stored on a secure Guy's and St Thomas' NHS Foundation Trust database accessible only to approved staff.

If you agree to take part, the donation of your samples and healthcare information will be treated as a gift to be used for research aimed at improving outcomes for those affected by heart and lung diseases.

Please note, samples will not be used for research related to reproductive cloning, termination of pregnancy or those involving animal research.

What happens if you say yes but then decide to change your mind later on?

You can change your mind at any time – you can let your doctor know or by using the contact details at the end of this information sheet.

If you do change your mind, you have two options:

1. Withdrawal from future contact but continue to have your samples and data used for research.

or

2. Complete withdrawal and destruction of your samples and data so it cannot be used again.

If you change your mind after a long time, the samples may have already been used. We cannot recall samples or information from researchers once they have been used. If, by then, your gift has already helped create new knowledge, that information cannot be undiscovered and will contribute to medical understanding.

However, we will dispose of any remaining samples and the research information so your gift will not be used in any further research.

What are the benefits to you?

It is unlikely that you will personally benefit from the research as it usually takes many years for advances to be made which help the way diseases are identified, treated and prevented. You can benefit from the knowledge that you are personally helping research to discover new ways of identifying, treating and preventing heart or lung diseases.

The tests and treatments you have received were developed with the help of patients who took part in research years ago. We believe research will make faster and more precise progress as more human samples are studied. Also, by using human samples the need to use animals in research may be reduced.

Who will be able to access your sample(s) and data?

The Biobank is managed by experienced doctors, researchers and database administrators who will ensure that your healthcare information and samples are only made available to those researchers who need to have access for an approved research study. Samples used by scientists will be coded so that they will not know who you are. Everyone handling your personal and medical details will be bound by a professional duty to protect your privacy.

All your personal details are kept strictly confidential and are de-identified in the research process. This means that personal information such as your name, address and any information that can identify you, are removed prior to sharing of data or samples.

Those who have access to your samples and data will be researchers focused on better understanding heart and lung diseases and how to treat them.

While most research will take place in the UK, there may be occasions where samples and data need to be sent outside the UK for approved research. Sharing samples internationally allows researchers to collaborate effectively and make faster progress in understanding and treating heart and lung diseases. Approved researchers may work for not for-profit organisations, such as research charities, universities or hospitals, and for profit (commercial) companies such as drug companies.

Researchers may publish the results of their research in medical journals. They may also present their results at scientific meetings. It is important for scientists and doctors to share results to help research advance as quickly as possible. You will not be identified when they do this.

Images such as your heart or lungs that have been obtained from a scan may be included in publications. These images will not include any information that could identify you.

In line with good practice for sharing of research findings, results from genetic research on your samples and health information may be published in controlled access databases. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information.

However, your genetic data and health information would not be labeled with your name or other information that could be used to identify you. Researchers approved to access information in the database will agree not to attempt to identify you. Sharing research results on controlled access databases will allow researchers from other organisations to use your information to study the causes of heart or lung diseases.

These databases may be located in countries outside of the United Kingdom. Data protection laws in other countries may not offer the same level of privacy protection as those in the UK, but none of your personal information or any information that can identify you, will be included on these databases.

Information on how Guy's and St Thomas' NHS Foundation Trust manages your data can be found on our website.

https://www.guysandstthomas.nhs.uk/research/research-and-development/data-and-research

Will I receive payment for donating samples to the Biobank?

You will not receive any payment for giving your sample(s) to the Biobank. Instead, your sample(s) and information will be treated like a gift with the aim of allowing research into the identification, treatment and prevention of heart and lung diseases.

Normally, we will take the sample(s) whilst you are attending a planned surgery, medical procedure or an outpatient appointment at Guy's and St Thomas' NHS Foundation Trust so you should not incur any additional expenses by donating a sample to the Biobank. If this is not the case, any costs incurred will be reimbursed.

Cost recovery for samples given to researchers.

The Biobank is managed to ensure that your samples and data are only made available to those researchers who have an approved research study. In order to keep this process viable and managed effectively the Biobank will charge researchers for the use of samples and data. However, this charge is purely for cost recovery purposes to cover any expenses of collecting, processing, tracking and storing of samples and data. The Biobank is a non-profit initiative and therefore does not charge for any samples and data to make a profit. Every study will require approval from the committee of doctors, scientists and patient advocates in the first instance and once the study is approved, researchers will then be charged for the samples and data they receive.

How will donating samples to the Biobank affect my hospital treatment?

Donating samples will have no effect on the treatment you are receiving. It is possible that your coded sample(s) may be used for genetic research to help us understand the genetic basis of heart and lung diseases. The results of these investigations are unlikely to specifically affect your care and will not be of diagnostic quality and so will not routinely be reported back to you. However, it is possible, though very unlikely, that the genetic research tests performed using your sample(s) will lead us to identify an abnormal gene which sometimes can run in families. You have the option of not receiving feedback on genetic results if this is your wish.

Alternatively, with your agreement, if we believe that an abnormal gene is important for your health or that of your family, we will inform your consultant or GP. They will explain what we have found and offer support and advice. Only the Biobank Manager and Biobank staff at the hospital will have access to the sample coding and will be the only members of staff who will contact your consultant or GP.

Who has reviewed these arrangements?

Biobanks must follow all current laws and ethical guidelines associated with tissue collection and use for research. This includes having a Human Tissue Authority licence and approval from a Research Ethics Committee. The Biobank policy and procedures have been reviewed by the South Central - Hampshire B Research Ethics Committee.

Further information

- If you would like to speak to someone about the Biobank, please contact the Biobank Manager, Harshil Bhayani on 0330 128 8456 or h.bhayani2@nhs.net.

- If you have any concerns that you are unable to talk to the Biobank team about, the Patient Advice and Liaison Service (PALS) may be able to help you. PALS is a confidential service and can be contacted via the hospital switchboard on 020 7352 8121 or pals@rbht.nhs.uk
- If you would like more information about research, please visit our website at: https://www.rbht.nhs.uk/research

Thank you for considering our invitation to support the Biobank.