

HEALTHY VOLUNTEER DONOR INFORMATION SHEET (>= 16 YEARS OLD)

King's College Denmark Hill Haematology Biobank (KCDHH): the collection and storage of blood and tissue for use in research studies into the causes, diagnosis and treatment of blood and bone marrow disorders.

Introduction

You are invited to take part in a Biobank which collects and stores tissue samples donated by patients and healthy volunteers to be used in research into blood and related disorders.

Before you decide, it is important for you to understand why this is being done and what it will involve. Please take time to read the following information sheet. Do talk to others about the Biobank if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. This information sheet describes what this is about and what it would involve for you.

Background

Blood is composed of blood cells and plasma. There are several different types of blood cell and each of these types has an important job. For example, red cells carry oxygen around the body, to provide energy. White cells help you to fight infection whilst cells called platelets stop you from bleeding and bruising.

Blood cells are made in the bone marrow in a tightly controlled manner to only produce the right quantity and type of blood cell the body needs. Some white blood cells also reside in lymph glands. Blood diseases, including blood cancers and diseases of red blood cells like sickle cell disease, can occur if this process goes wrong: for example, when too few or too many blood cells or the wrong type of blood cells are made. Abnormal blood cells may form in the bone marrow or lymph glands, and also be present in blood. We do not fully understand how the production of normal blood cells is controlled. We also do not fully understand why blood production processes become abnormal. However, we think that abnormalities in the function of genes in blood cells, including the presence of 'mutations' (mistakes in the genetic code) are likely to be important.

What is the purpose of the Biobank?

The Biobank will collect donated tissue samples, plus information about donors, for use in medical research. The biobank has ethical approval to take care of samples and make certain

that they are shared properly. These projects include ones studying the causes of blood cancer; the effects of drugs on, and the development of new drugs to treat blood disease. Researchers may test samples for genetic abnormalities which may contribute to causing blood disease. Researchers may create cell lines from patient samples for research. This is when blood cells are extracted from your donated sample and then grown in the laboratory (in a petri dish) to generate more cells and provide material which can be subsequently used for research. These cell lines may have the potential to be grown for many years.

Researchers may also use patient samples in research involving the use of experimental animals. The KCDHH Biobank is funded and sponsored by the King's College London. The Biobank is based at the Rayne Institute, 123 Coldharbour Lane, London, SE5 9NU, which is part of the King's College London. The Biobank laboratory here will process and store donated samples under license by the Human Tissue Authority (HTA). The designated individual for this license is Dr Claire Troakes.

Why have I been invited?

You have been asked to participate because you are a healthy individual who does not have a blood or bone marrow disorder.

Do I have to take part?

No, taking part in the Biobank is entirely voluntary. If you do decide to participate, you are free to withdraw from the Biobank at any time without giving a reason and your future treatment will not be affected.

What will happen to me if I decide to take part?

If you decide to take part in the Biobank, a specialist nurse, Biobank staff or doctor will talk to you about the Biobank. They will be able to discuss the Biobank with you and answer any questions you may have before asking you to sign a consent form.

We will also ask if you would agree for donated samples and collected data to continue to be made available for research after you die, without us having to seek additional consent from your next of kin.

What types of samples will be collected?

We may collect blood (typically 20mls or four teaspoons) which can be collected at any time, or bone marrow (typically 10mls or two teaspoons). We would only ask for your bone marrow

if you are already having this procedure done for another clinical reason, or are having an operation for clinical reasons (e.g. having a hip replacement or heart surgery), where bone marrow tissue may be accessible. We are asking you to allow a sample of this bone marrow to be collected during your procedure for research purposes.

Collecting these samples takes about 1 minute, and in the case of a bone marrow sample, will not otherwise affect the procedure or your care after the operation. If you have donated a bone marrow sample, you will undergo routine observation while in hospital and you will be followed up as part of your routine surgical care.

We would also like to take a sample of scalp hair follicles (10 hairs or more), nail clippings (10 or more, from hands or toes) or a skin biopsy (a small piece of skin tissue taken from the same site as your procedure) or saliva by doing a mouth wash. We will use these samples to extract genetic material and compare this to the genetic material in your blood and bone marrow.

Are there any possible disadvantages or risks of taking part?

Taking part in the Biobank should not cause you any harm. Taking a blood sample is a low risk procedure, where the risk of complications (e.g. bruising, bleeding) is <1% (or less than 1 in 100). Bone marrow samples taken during an operation and should not cause any problems either during your operation or afterwards when you go home.

If I am donating bone marrow, does my surgeon know about this project?

Yes. He/ she would have identified you as a potential participant for our Biobank.

What will happen to my samples once they have been taken?

The sample taken for the Biobank will be send to the Biobanking laboratory in King's College London for further processing and long-term storage.

Researchers (Academic and Commercial) can then apply to the Biobank to request access to banked samples in order to carry out research. This research may involve some of your bone marrow cells being grown in the laboratory to see how they develop into red cells, white cells, platelets, or other cell types. We may also extract genetic material from your bone marrow cells to study how genes work during the process of making blood cells. As your blood tests are normal these laboratory tests will tell us what the normal results should be.

The type of research carried out on your samples will be reviewed by a committee of experts to ensure that they are most likely to provide benefit to the blood disease research community and to patients. The committee will prioritise applications from academic groups where their proposal has been reviewed by an independent panel (called peer-review). When considering applications from Commercial bodies, we would prioritise those applications where there is evidence of close collaboration with an Academic (i.e. a non-commercial) research group.

The Biobank will not be able to accept any donations if you choose to place conditions on the use of samples, except for in research involving animals. You will be asked to consent or decline for your samples to be used for research that involves animals.

Will there be circumstances where I will not be allowed to take part?

You need to be 16 years old or older to take part. We want to ensure that everyone taking part in KCDHH are doing so in a fully informed manner, of their own free will. Therefore, you will not be permitted to take part in KCDHH if you are unable to provide valid, informed consent.

We also want to reduce the risk of exposure to transmissible pathogens in research staff and would therefore exclude collection of samples from donors known to be infected with the human immunodeficiency virus (HIV), hepatitis B virus and hepatitis C virus.

Can I find out the results of the research on my sample?

We do not routinely report individual results as our research involves testing large numbers of samples from many different people to try to identify factors that influence disease. However, research findings using KCDHH Biobank samples will be published in peer-reviewed scientific and medical journals. KCDHH will also publish our activities (e.g. how many patients recruited, how many samples used for research etc.) every year and this information would be publicly available.

However, from time to time, we may detect unexpected abnormal findings from your donated sample, which, if confirmed, may need clinical monitoring or treatment. Very rarely, we may also detect unexpected findings that may affect your relatives (for example inherited genetic abnormalities). We will ask you if you wish to be informed of such findings. If you consent to this, the Biobank team will refer you to your treating clinician to arrange for further assessments or tests if these are appropriate.

Our findings often need many years of further research to prove if they are truly important. Our research is not done for profit but may involve commercial companies. You will not benefit financially if your samples are used to help develop valuable new treatments or tests.

Will my taking part in this Biobank be kept confidential?

All personal information that is collected about you will be kept strictly confidential and will only be accessible to the named KCDHH Biobank staff who need to know this information for administrative purposes. This personal information is linked to a unique patient identification number for the purposes of KCDHH. Thereafter, samples and documentation related to you and your sample in KCDHH will only be identified by this identification number. This information is stored securely on a computer where data is encrypted and access is password controlled. Any samples and accompanying data that are sent to researchers will be anonymised so that you cannot be recognised from them. Non-personal information (e.g. age, gender, diagnosis) may be shared with relevant researchers.

In order to ensure that the Biobank was being managed correctly, for monitoring and audit purposes your records may be read (but not kept) by members of the KCL HTA Governance Group, King's College London. Other relevant regulatory bodies would also have access to such records (such as the ethics committee and human tissue authority).

What kind of information about me will you collect?

If you agree to take part, your doctor and local research team keep a record of your personal information and know that you are taking part in KCDHH Biobank. A copy of your signed consent form which will have some personal information will be forwarded to the KCDHH Biobank staff to confirm that you are taking part. However, this personal information will not be passed onto researchers.

We will ask your doctor and local research team to collect a set of non-personalised information which are relevant to your blood and/or bone marrow donation that will be passed onto KCDHH staff, and may be passed onto other researchers. This will include age at time of sample collection, gender, type of surgery (for bone marrow samples) and tests results relevant to your blood and/or bone marrow donation (e.g. full blood count).

How long will you keep identifiable information about me?

King's College London will store the anonymised research data and any research documents with personal information, such as consent forms, securely at the King's College London for as long as it is required from the relevant regulatory bodies after the end of the biobank. The team at your local hospital site will keep identifiable information about you for as long as their organisational policies determine.

Who is looking after the collected information?

King's College London is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. You can find out more about how we use your information by contacting the Biobank Data Manager.

Can I access, change or remove my information?

Your rights to access, change or remove your information are limited as we need to manage your information in specific ways in order for the Biobank and all research projects to be reliable and accurate.

Will I be reimbursed for taking part?

No. We are unable to provide any monetary reimbursement for participating in biobanking.

Can I change my mind and withdraw from the Biobank?

You may also withdraw from the Biobank without having to give a reason if you so wish at any point. If you withdraw from the Biobank, the data and samples already collected from you will be used for future research unless you specifically withdraw consent for this. Samples and data that have already been processed and used in analysis cannot be withdrawn.

Will my donated samples or clinical data be used by researchers after my death?

Your donated samples and clinical data collected while alive may be used by researchers after your death. We will not inform your next of kin of your participation in the biobank and therefore will not be seeking additional consent from your next of kin to use samples and data you had previously donated for future research. We do not collect samples from individuals after death.

What are the possible benefits of taking part?

There will be no direct benefit to you specifically in taking part in this Biobank. However, we hope that research using donated samples will help patients with blood diseases in the future.

What if there is a problem?

King's College London takes responsibility for the Biobank and has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in the Biobank. NHS indemnity operates in respect of the clinical treatment which is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated during Biobanking process, in the first instance you should contact the Biobank Data Manager.

You may also contact the Director of Research Management and Director of Administration (Health Schools), King's College London, Strand, London, WC2R 2LS.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this Biobank.

Who has reviewed the biobank?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests.

What do I do next?

If you would like to participate in this Biobank, a member of the research team will go through this information with you to make sure that you have the opportunity to ask questions and that you fully understand the information provided. We would then ask you to sign the Consent form. If you require further information, please do not hesitate to speak with your Doctor or contact the KCDHH Biobank Manager.

Thank you for taking time to read this information sheet and your interest in donating samples to our Biobank.

Dr Lynn Quek

Biobank Chair

On behalf of the KCDHH Biobank Governance Committee