PATIENT 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 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 important job. For example, red cells carry oxygen around the body, to provide energy. White blood cells (also known as immune cells) help you to fight infection whilst cells called platelets stop you from bleeding and bruising. Plasma is the fluid that carries the blood cells around the body.

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 King's College London. The Biobank is based at the Rayne Institute, 123 Coldharbour Lane, London, SE5 9NU, which is part of 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?

Your doctor thinks you require tests which involve a bone marrow, blood or lymph tissue biopsy to help decide whether or not you have a blood disorder. In some cases, you will have already been diagnosed with a blood disorder but you now require follow-up or reassessment tests.

We would like to ask your permission to use additional or surplus samples from the test procedure for research purposes. In addition, we would like to collect a sample of non-blood tissue such as urine, faeces**,** hair, nails, saliva or a small piece of skin (taken at the same site as bone marrow or tissue biopsy) saliva (from a mouth wash), for comparison with your bone marrow, blood or lymph tissue samples.

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.

In most cases, the samples are taken at the same time as your biopsy or test procedure and there will be no need for an additional biopsy. Giving extra research samples means your routine test may take slightly longer. Our research tests will not affect your standard medical care.

Although we ask patients to provide samples in addition to those required for clinical purposes, we will also bank samples which are surplus to those required for clinical purposes which would otherwise be thrown away, to make sure no material is wasted.

We will be collecting personal information about you and your diagnosis at the time of sample collection. We may also collect information from any follow-up clinical care relevant to your blood disease. This information will enable the Biobank to relate your donated samples with your diagnosis and clinical outcome. 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.

If you agree to take part in the Biobank, we will verbally confirm your consent before we take samples which are being collected as part of your routine care (for example if your doctor has requested a repeat blood or bone marrow test).

There may be patients who have had a biopsy performed for clinical purposes before their referral to a Haematologist with a suspected or confirmed blood disease. We would like to invite these patients to take part in the Biobank, and will ask for their consent to store surplus or leftover material from the previous biopsy.

Occasionally, we may ask patients to provide an additional sample when it is NOT required for a clinical purpose. These may be patients who have a particularly rare condition, and/ or where the initial sample was not adequate for banking. We may ask such patients for specific permission to perform an additional procedure to sample blood, bone marrow or lymph tissue biopsy, where the risk of complications (e.g. bruising, bleeding) in the patient is <1% (or less than 1 in 100). We will discuss the potential risks of these additional procedures with you.

What types of samples will be collected?

The type of sample we will collect depends on the type of biopsy or test procedure you are having. We may collect blood (typically 20mls or four teaspoons), bone marrow (typically 10mls or two teaspoons) or lymph tissue or other blood cancer tumour. Bone marrow

samples are usually collected from a pelvic bone called the ilium, situated near the base of the spine, at the top of the buttock. These samples may be liquid (or 'aspirate') collected using a hollow needle, or small solid piece (~2cm in length, 2mm in diameter, called a 'trephine') also collected using a specialised needle. Lymph tissue is commonly from a lymph gland, which are distributed all over the body and consist of white blood cells that form our immune system. These cells help fight infection by attacking and destroying germs. Sometimes blood problems also occur in lymph tissues. Very rarely, blood cancers can manifest as a solid tumour (sarcoma) in different parts of the body, including the skin. We may collect lymph or tumour cells via a 'fine needle aspirate' where a small sample is sucked up using a needle no larger than those used for taking blood samples. Alternatively, we may collect larger pieces of tissues via a full biopsy. Whereas bone marrow biopsies and fine needle aspirates are typically carried out using local anaesthetic, other biopsies may be carried out under general anaesthetic depending on the biopsy site. These are tissues where, your doctor thinks, your suspected or known disease is present.

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 bone marrow or lymphoid or tumour tissue biopsy) 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, bone marrow or lymph tissue samples. We would also like to take a sample of urine or faeces for other types of biological analysis.

Are there any other tests or aspects of this Biobank I have committed myself to?

For the majority of patients taking part in KCDHH, there are no additional tests and no additional hospital visits above and beyond what is recommended by your doctor for your clinical care (e.g. monitoring/ reassessment of disease). If your doctor thinks you require additional blood, bone marrow or lymph biopsies in future, we will confirm your ongoing consent verbally, and collect a sample from these follow-up tests.

In some cases, if you have a condition which is of particular interest, or which is rare, we may ask you if you would consider giving additional samples above those required for clinical monitoring, *i.e. an additional test procedure for research purposes only. This would usually be procedure with a low risk of complications (e.g. taking a blood sample, or to suck up small sample of cells from a lymph node using a small, fine needle). Very rarely, we may also ask patients if they would consent to have a procedure such as a bone marrow or lymph node biopsy, where there is a greater risk of side effects or complications. The doctor asking you to consider additional procedures for research purposes will explain to you the risks of the*

procedure and ask for your specific consent. On all occasions, participation is entirely voluntary. You may refuse consent to donate as part of an additional procedure but, still participate in the biobank by donating as part of a routine procedure.

Are there any possible disadvantages or risks of taking part?

Taking part in the Biobank should not cause you any harm. The samples will be taken as part of the routine biopsy or test procedure. Occasionally, we may ask patients to provide an additional sample when it is NOT required for a clinical purpose (see earlier section).

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

The additional sample taken for the Biobank will be sent 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. The type of research which will be carried out on your samples could involve testing cells for various properties in the laboratory, studying how different genes are expressed when cells are grown or exposed to drugs and extracting genetic material for testing for gene mutations. 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?

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 may need clinical monitoring or treatment above and beyond the disease(s) you have already been diagnosed with. 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.

We might use your samples to test if promising new treatments or investigations might be suitable for patients in the future.

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 is 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. 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 clinical condition that will be passed onto KCDHH staff, and may be passed onto other researchers. This will include age at time of sample collection, gender, clinical diagnosis and tests results relevant to your diagnosis. We may then collect follow-up data to see if your condition has changed, or if you have received treatment for your condition.

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 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. There will be no extra visits to the hospital other than those planned for your normal clinical care and hence, no payment or travel reimbursement will be made for participating in this Biobank.

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?

We are unable to say if there will be any 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 the Biobanking process, in the first instance you should contact the Biobank Data Manager. The Biobank Data Manager will perform an internal investigation into the

complaint and this will be raised with the committees which govern the Biobank. We will endeavour to report back on committee findings within three months of the complaint.

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