

## **PATIENT INFORMATION SHEET**

### **Manchester Cancer Research Centre Biobank**

#### **Consent to Storage and Use of Blood and/or Bone Marrow for Research**

##### **Invitation**

You are being invited to donate ('gift') to the Manchester Cancer Research Centre Biobank. Before you decide whether or not to agree to donate your tissue, it is important that you understand why the Biobank is needed and what donating samples will involve. Please take time to read the following information carefully and discuss it with relatives, friends and/or your doctor or nurse if you wish. Please ask if there is anything that is not clear to you or if you would like more information.

##### **What is a Biobank?**

A Biobank is a stored collection of blood, bone marrow, tissue and other samples taken with informed consent from patients with different illnesses. The Manchester Cancer Research Centre Biobank, located in South Manchester at The Christie NHS Foundation Trust site, was started in 2007 with the aim of collecting large numbers of tissue specimens from many patients with diseases such as cancer and leukaemia.

##### **Why is a Biobank needed?**

These tissue specimens are needed to help medical researchers improve their understanding of human disease and to develop new or improved treatments that might increase the chance of cure or prolonged survival. Although a lot of progress has been made in recent years, and some new drugs have been developed, there is always a lot more work to be done.

In research centres across the United Kingdom, including the Manchester Cancer Research Centre, doctors are investigating blood diseases such as leukaemia, lymphoma, myeloma, myelodysplasia and myeloproliferative disease. One important way to make this task much easier is to collect and store blood, bone marrow and other samples taken from patients when they are diagnosed with their condition, and from time to time thereafter. These samples can later be analysed in carefully reviewed research projects.

##### **Why have I been contacted?**

You are either known to have a blood disorder, or your doctor suspects that you might have a blood disorder. He or she is planning to perform a blood test and/or a bone marrow test to investigate or monitor your condition.

### **Donation of a blood sample**

If it is thought that you have abnormal cells in your blood, we would like your permission to collect and store a blood sample. If you agree, your doctor, nurse or phlebotomist will take an extra 20-40mls of blood (two to four dessertspoonfuls), in addition to the samples needed to investigate your condition. The blood sample will be taken safely in the usual way, either through a Hickman line or through a vein in your arm using a small needle.

In a small number of patients with blood disorders, blood cells are sometimes collected using a procedure called leucopheresis, or blood is removed using a procedure called venesection. If either of these procedures are required, your doctor will have explained the details to you and the reasons why it is necessary. We invite you to donate any left-over blood cells from these procedures, after all of the clinical tests have been completed, to the Biobank.

### **Donation of a liquid bone marrow sample**

In addition to blood tests to investigate your condition, your doctor may be planning to perform a bone marrow test. The details of this test will be explained to you by your doctor or nurse.

If a bone marrow test is planned, we would like your permission to collect an extra 10-20ml sample of liquid bone marrow for the Biobank (about two dessert spoonfuls) at the same time as liquid bone marrow is collected for the other tests that are needed to investigate your condition. Although bone marrow tests can sometimes be uncomfortable, your doctor or nurse will do their best to minimise this. The taking of an extra liquid bone marrow sample is safe and will cause minimal further discomfort, over and above that associated with the test itself.

It is important to understand that the priority of the doctor or nurse performing the test will be to collect enough liquid bone marrow to investigate your blood disorder properly. Only if there is enough liquid bone marrow to perform the hospital tests will any extra bone marrow be collected for the Biobank.

Sometimes there may also be left over liquid bone marrow material once the hospital tests (e.g. flow cytometry or cytogenetic studies) are fully completed. If this is the case, we invite you to donate this material as well to the Biobank.

### **Donation of bone marrow biopsy material**

In addition to the collection of liquid bone marrow described above (called a bone marrow aspirate), as part of the normal investigation of your blood condition it is often necessary to collect a small sample of solid bone marrow at the same time. This is called a bone marrow trephine biopsy.

In a small number of cases, where the bone marrow biopsy sample is of sufficient size, we may ask your permission to use any excess material for research.

### **What happens if, in the future, my doctor needs access to my stored blood and/or bone marrow material to perform tests that might help with my treatment?**

In the unlikely event that this was necessary, the Biobank would always provide your doctor with any remaining stored blood and/or bone marrow samples that would assist with your treatment.

### **Obtaining your consent**

If you agree to donate your samples, you will be asked to sign a consent form. Please read it carefully, initial the boxes where indicated and then sign the form. You may be participating in a clinical research trial. Your decision to donate to the Biobank will not affect your participation in this trial.

### **Donation of samples collected previously**

You may have had tests performed previously, either recently or in the more distant past, and there may be material leftover that is no longer needed for clinical purposes. These samples are typically archived for many years within the diagnostic laboratory.

We would like your permission to collect and store such leftover samples for use in future research projects once all necessary diagnostic tests have been completed.

If you would prefer that we do not use past samples for research, please leave the relevant box on the consent form blank.

### **Consent for storage samples taken in the future**

Sometimes, patients with blood disorders have repeated tests over a number of months or years. We invite you to donate samples taken in the future as part of the treatment your blood disorder.

It is important to be clear that we will not ask you to have a bone marrow test simply to obtain material for the Biobank. Bone marrow tests will only be performed when medically required as part of the investigation and treatment of your blood disorder.

If, however you would prefer to give your consent on each occasion that your blood and/or bone marrow are sent to the Biobank, please leave the relevant box on the consent form blank.

### **What will happen to my tissue?**

If you agree to donate your samples, we will arrange for it to be sent to the Manchester Cancer Research Centre Biobank at The Christie where it will be stored securely. Your donation will be used in research projects which have been carefully reviewed for quality by the Biobank's scientific committee. Only high quality applications which meet strict ethical standards will be approved. Some of these projects may involve the use of mice as experimental animals.

We may use the cells taken from your blood and/or bone marrow to create a type of cell known as a pluripotent cell. This type of cell can be used to create different types of tissue and these cells might be used in research involving genetic alteration of the cells.

Your tissue will not be used for non-medical or non-scientific purposes.

### **Will commercial companies have access to my samples?**

Research groups in both academic institutions and commercial companies will be able to apply to the Biobank's scientific committee to use stored samples. Research by commercial companies may greatly assist in the development of new drugs or tests to treat leukaemia and other blood disorders. These projects could involve portions of your samples being exported to research laboratories in other countries worldwide.

If you would like to donate tissue to the Biobank but do not want it to be used by commercial companies please leave the highlighted box on the consent form blank. This will ensure that your samples are supplied only to academic organisations (for example, universities or research institutes) and not to any commercial organisations.

### **Genetic testing**

Some of the projects performed may require DNA (genetic material) to be extracted from your sample. We invite you to give permission for DNA extraction and testing so that research groups can try to find out what gene patterns may increase the risk to others of your blood disorder and to see whether we can predict which future treatments for your blood disorder may be best. All genetic testing on your sample will be done in a research setting. On very rare occasions, there may be an instance where a research result may have future implications for you and will need to be repeated in a clinical setting. If this is the case, your clinical team will be informed through the appropriate channels.

### **Will I need to donate any other samples?**

In some cases, researchers investigating the genetics of cancer also need to compare the DNA in your cancer cells to DNA in your blood cells. The easiest way to do this is to collect either saliva or by taking a buccal swab, which is a simple swab on the inside of the mouth to collect cheek cells. We would like to ask your permission to donate either a saliva sample or a buccal swab for this purpose.

We may also like to collect other samples, such as plucked hair or other fluids such as ascites (a fluid build-up in the abdomen in certain conditions). We will not need to collect these samples in every case, and we will tell you in advance which samples we would like to collect and how this will be done. It is completely up to you to decide what samples types you are happy for the Biobank to collect and store from you, and this will be detailed on the consent form.

**Will the Biobank collect any information about my case?**

If you agree to donate your samples to the Biobank, we will also collect information about your case to help researchers understand what your blood disorder was like. This will be kept on a secure computer in the Biobank and will be treated confidentially. Any information that leaves the Biobank will always be anonymised, so that the researchers who work on the sample will not be able to identify you personally.

We will need to review your medical notes at regular intervals to make sure that the details we have about your case are correct. This will be done by a healthcare worker employed by the Biobank.

**Do I have to take part?**

No, there is no obligation to donate your samples to the Biobank. If you do not wish to donate your samples, this will not affect the treatment given to you by your doctors now or in the future in any way.

**What happens if I change my mind?**

If you decide to donate tissue today, but later change your mind, you are free to withdraw your donation at any time in the future without giving a reason, and without affecting the care you receive. If you choose to do so, please contact the Biobank:

Contact Person: Jane Rogan  
Postal address: MCRC Biobank  
The Christie NHS Foundation Trust  
Manchester  
M20 4BX  
Telephone number: 0161 918 2110  
Email: jane.rogan@nhs.net

Upon receipt of your request to withdraw, your samples would then be destroyed, and a letter of confirmation sent to you. Depending on when you decide to withdraw your permission, it is possible that some research may already have taken place on your blood or bone marrow samples. We would, however, ensure that no further research work is done.

**What are the benefits of taking part?**

There will be no direct benefit to you from donating your tissue. Your donation will however contribute to research that may help in the discovery of new tests and treatments for blood diseases.

**What happens if new information about my case is found by researchers?**

It is very unlikely that information directly relevant to your care or treatment will be discovered by researchers using your blood or bone marrow. If this happens we would immediately notify the medical team looking after you.

**Will anybody make a profit from my tissue?**

The Manchester Cancer Research Centre Biobank will not profit financially from supplying blood and/or bone marrow samples to researchers, although a charge will be made to cover staffing, processing and storage costs.

If a new test or treatment is developed by a commercial company or an academic group as a result of work performed on tissue samples supplied by the Biobank, that company or group may then make a profit and file patents as a result of their discoveries. It will not be possible for you or the Biobank to make a claim. However, any test or treatment that is developed may benefit all of us in the future.

**For further information:**

If you would like further information on the Manchester Cancer Research Centre Biobank please ask the doctor or nurse who is treating you, or visit our website at [www.mcrc.manchester.ac.uk](http://www.mcrc.manchester.ac.uk). If you have a comment or complaint, contact the Biobank Manager:

Contact Person: Jane Rogan  
Postal address: MCRC Biobank  
The Christie NHS Foundation Trust  
Manchester  
M20 4BX  
Telephone number: 0161 918 2110  
Email: jane.rogan@nhs.net