



PATIENT INFORMATION SHEET

Manchester Research Centre Biobank

Consent to Storage and Use of Samples for Research

Invitation

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

Why do we need the Biobank?

A lot of progress has been made recently in understanding cancer. However, further research needs to be done to help us understand the causes of cancer and also to discover new methods for diagnosis and treatment. It is very important that we have a large number of tissue specimens, blood and other samples from people with and without cancer to allow this extra research to take place. It is also important that we have information about the people who give samples so that we can relate what we find in our research to what happens to patients. This is because cancer is not a single disease and the way it affects individuals varies from person-to-person. The Manchester Cancer Research Centre Biobank aims to help researchers by collecting large numbers of tissue samples, blood and other samples from people with many different types of cancer along with samples from people who have not been affected by the disease.

Why have I been contacted?

You have recently undergone investigations into a medical complaint, and have been referred for further assessment and/or surgical intervention. An operation is planned to remove some tissue. We would like to ask you to donate some of this tissue to us as a gift so that we can store it carefully in the Biobank in order to help with cancer research projects. If you have a rare tumour your donation will help researchers better understand these types of cancers. We would also like to ask permission to retain a sample of the neighbouring non-involved tissue that is routinely removed during the operation as this can be useful to compare with any diseased tissue that is removed.

Will donating tissue affect my treatment?

Donating your tissue samples will not affect your treatment. In most cases, we aim to only collect any left-over tissue from samples removed as part of routine care. Occasionally we would like to collect extra tissue from a biopsy you might be having for routine care or a clinical research trial, but we would only do this in agreement with your doctor to make sure it would not cause you any further discomfort. In these cases, donation of any additional tissue would not affect your treatment or your participation in the clinical research trial.

Do I need to give a blood sample and what will happen to this?

We would like to ask you to donate a blood sample to the Biobank as well as tissue. This sample can be taken at the same time as any routine blood tests you need. In most people we will take a 25ml (two and a half dessertspoonfuls) sample. Occasionally we would like to take a 50ml (five dessertspoonfuls) sample so that the white blood cells can be separated and stored. This will allow research on the functioning of the immune system to be carried out.

Do I need to give a urine sample and what will happen to this?

This sample (about 20ml- two dessertspoonfuls) is passed into a sterile pot in exactly the same manner as if we were testing you for a urine infection. This will be stored with your blood sample and will enable researchers to test to see if markers seen in the blood are cleared from the body via the kidneys.

What other samples will I need to donate?

We may also like to collect other samples for the Biobank, such as plucked hair or other fluids such as saliva or 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.

Donating tissue from previous operations

If you have had a previous operation or biopsy, researchers often would like to compare any left over tissue from this with any samples collected at a later date, so they can look at how and why disease changes over time. These samples will now be stored in the pathology laboratory of the hospital you had your previous surgery or biopsy but we would like your permission to request these samples and store them in the Biobank for such projects. If you would prefer us not to request and store any samples from previous operations or procedures, please just leave the relevant box on the consent form blank.

Donating samples from future operations

It may be that you will return to this hospital or another hospital for another procedure in future and we would like your permission to collect samples from these as well. If you would prefer us to approach you each time for each procedure, you can leave the relevant box on the consent form blank and we will ensure we ask your permission for each procedure you are having.

Research Biopsies

In many current research projects to understand the cause and investigate and find new treatments for cancer, extra tissue samples are needed from patients in addition to any samples collected for diagnostic purposes – this is called a ‘research biopsy’.

We are asking for your consent to collect a research biopsy, which would involve an extra hospital visit and biopsy procedure to donate tissue samples for research purposes only.

Research biopsies are entirely optional and even if you consent at this point, you would still be contacted separately by a doctor to discuss the type of procedure that is proposed to collect any samples as safely as possible at a time and date that works for you. All procedures will be carried out by fully qualified medical staff and you will give your consent separately to this prior to any procedure taking place.

Any collected samples will be used in exactly the same way as other samples donated to the MCRC Biobank in line with your consent and access to samples will be heavily regulated to ensure they are only used for high quality cancer research projects. Further information about the specific research project in which your samples are being used will also be provided to you before any research biopsy samples are taken.

Whilst all sample donations are freely given, any expenses you incur with additional hospital visits will be reimbursed.

As with any other Biobank donations, your treatment or care will not be impacted by your decision, and you may withdraw your consent at any time.

What will happen to my samples?

If you decide to donate your samples, we will arrange for these to be sent to the Biobank at The Christie, where it will be stored securely. Approved research groups across the world will use your gift of tissue. In all cases, before they are given access to your gift, the quality of the application will be measured by a group of expert scientists and doctors who work in the same field. Only high quality applications which meet strict ethical standards will be approved. Your tissue will not be used for non-medical or non-scientific purposes.

What types of research will be done on my samples?

All samples collected by the MCRC Biobank will be used to further understand cancer, its development and look at new ways to diagnose and treat the disease. This research may, for example, involve identifying markers that will allow us in the future to predict

better how aggressive an individual's disease is and also which treatments would be most appropriate for each patient.

We may use part of your sample to obtain DNA (genetic material). We are asking you to allow us to extract DNA so that research groups can try and find out what gene patterns may increase the risk of different types of cancer or to see whether we can predict what treatment 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 commercial companies have access to my samples?

Research groups in both academic institutions and commercial companies will be able to apply to use samples stored in the Biobank. Research by commercial companies may result in the development of new drugs to treat cancer. 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 relevant box on the consent form blank. This will ensure that your samples are not supplied to any commercial organisations.

Will the Biobank collect any information about my case?

If your tissue is stored in the Biobank, we will also collect information about your case. This will be kept on a secure computer in the Biobank. This information may help researchers to make comparisons between samples from patients with and without cancer. We would like to review your medical notes and related records at regular intervals to update the information we hold and a healthcare worker employed by the Biobank will do this. All information which is collected about you will be kept strictly confidential. Any information that leaves the Biobank will be anonymised so that the researchers who work on your tissue samples will not be able to identify you personally.

Do I have to take part?

No, there is no obligation to donate your samples to the Biobank. If you decide to give us your samples you will be asked to sign a consent form. You are still free to withdraw at any time without giving a reason. If you decide not to take part, the samples removed will still be processed routinely. The treatment or care you will receive will not be affected.

What happens if I change my mind?

You have the right to withdraw your donation at any time. If you choose to do so, please contact the Biobank;

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

The samples will be destroyed and a letter of confirmation will be sent to you. Depending on when you decide to withdraw some research may already have taken place on your samples but we will 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 samples. Your donation will however contribute to research that may help in the discovery of new tests and treatment for cancer.

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

It is very unlikely that information directly relevant to your care and treatment will be discovered by researchers using your samples. If this happens we will notify the medical team that are looking after you.

Will anybody make a profit from my tissue?

The Manchester Cancer Research Centre Biobank will not benefit financially from supplying samples to researchers although we may make a charge to cover the time and materials required to process and store the samples.

Analysis of specimens is only one of many stages in the development of new diagnostic tests and treatments. Usually, samples from lots of people will be analysed in each research project. If a new test or treatment is developed, a commercial company (pharmaceutical) or academic 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. 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 research nurse who is treating you. Alternatively, you can visit our website on www.mcrc.manchester.ac.uk or contact the Biobank;

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